S. Hrg. 99-687

TO AMEND THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

HEARINGS

BEFORE THE

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY
UNITED STATES SENATE

NINETY-NINTH CONGRESS

SECOND SESSION

ON

S. 2215

A BILL TO AMEND THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT TO ENSURE SAFER PESTICIDES AND TO BETTER PROTECT THE PUBLIC AND THE ENVIRONMENT, AND FOR OTHER PURPOSES (FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT AMENDMENTS OF 1986)

AND

S. 2346

A BILL TO AMEND THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT TO ENSURE SAFER PESTICIDES AND TO BETTER PROTECT THE PUBLIC AND THE ENVIRONMENT, AND FOR OTHER PURPOSES (PESTICIDE REFORM ACT OF 1986)

APRIL 22 AND 30, 1986

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TO AMEND THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

TUESDAY, APRIL 22, 1986

U.S. Senate,
Committee on Agriculture, Nutrition, and Forestry,
Washington, DC.

The committee met, pursuant to notice, at 9:40 a.m., in room SR-332, Russell Senate Office Building, Hon. Richard G. Lugar, presiding.

Present: Senators Helms, Lugar, McConnell, Zorinsky, Leahy, Melcher, Dixon, and Heflin.

STATEMENT OF HON. RICHARD G. LUGAR, A U.S. SENATOR FROM INDIANA

Senator Lugar. This hearing of the Senate Agriculture Committee is called to order.

I appreciate the opportunity to chair the hearing this morning to discuss the reauthorization of the Federal Insecticide, Fungicide, and Rodenticide Act.

The committee has before it two bills. The first is compromise legislation introduced by myself, Senator Proxmire, and Senator Leahy which is supported by the National Agricultural Chemical Association and the campaign for pesticide reform. The second is another coalition bill supported by the Chemical Specialties Manufacturing Association and the American Farm Bureau Federation. This legislation was recently introduced by the distinguished chairman of the Agriculture Committee, Senator Jesse Helms.

I would simply indicate at the outset of these hearings that I am grateful for the spirit of bipartisanship that has been displayed in the negotiations thus far. While we still have major differences to overcome, I believe that all groups should be commended for their openminded approach to each of these complex issues. Without such cooperation, the reauthorization process would not have come this far.

While there has indeed been a spirit of bipartisanship and cooperation, I am also aware that our colleagues in the House of Representatives have done some work in preparing a statement of differences between the various proposals. This document is now an overwhelming 143 pages in length. My reading of the situation suggests little desire among the members of this committee to deal with differences of this size and magnitude given our overwhelming agenda of budget and tax matters for the remainder of this session of Congress.

This committee has, in my opinion, two options for progress in the reauthorization process. There simply must be further dialog and compromise among the competing interests. Also, this committee in cooperation with EPA will have no choice but to consider narrowing the scope of these issues.

I am aware that much of the proposed changes to FIFRA are simply the result of current EPA policy and regulations being codified in the FIFRA statute. In these instances, I believe the committee could limit the scope of these amendments by giving serious thought to simply maintaining current law and continue to give the EPA some latitude to modify its regulatory program.

I look forward to a thorough hearing on these complex and difficult issues. I am grateful to each of you who have come to the hearing today for your devotion of time and resources to these negotiations and to your preparation of testimony.

Let me state for the record that as other Senators appear and have opening statements, the Chair will recognize them and will make each of those statements a part of our hearing record.

We are pleased to have two sessions of hearings today. In the morning session we will be hearing from the EPA and from the U.S. Department of Agriculture, and in the afternoon session, from a variety of witnesses of various points of view in the public and private interests.

The Chair would like to call to the table now for testimony, which we know will be comprehensive and important to setting our record, Jack Moore, Assistant Administrator, Pesticides and Toxic Substances, the Environmental Protection Agency.

Mr. Moore, would you please come to the table?

Senator Alan Dixon, the distinguished Senator from Illinois, has just joined us, and the Chair welcomes Senator Dixon.

Senator DIXON. Good morning, Mr. Chairman.

Senator LUGAR. Do you have any opening comments, Alan, before we proceed with the testimony by Mr. Moore?

Senator DIXON. Yes. If I could have leave to just put a very short statement in the record, Mr. Chairman.[1]

Senator LUGAR. Very well. By unanimous consent, it will be made a part of the record.

Mr. Moore, would you please introduce your associate and then proceed with your testimony?

STATEMENT OF JOHN A. MOORE, ASSISTANT ADMINISTRATOR, PESTICIDES AND TOXIC SUBSTANCES, ENVIRONMENTAL PROTECTION AGENCY, ACCOMPANIED BY STEVE SCHATZOW, DIRECTOR, OFFICE OF PESTICIDE PROGRAMS

Mr. MOORE. Yes, Senator. I have with me this morning Mr. Steve Schatzow, who is the Director of the Office of Pesticide Programs at EPA.

Senator LUGAR. Welcome. We are pleased that you are here.

Mr. MOORE. Senator, with your concurrence, I would like to summarize my testimony and ask that the whole 30-odd pages be submitted for the record.[2]

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[1] See p. 126 for the prepared statement of Senator Dixon.

[2] See p. 129 for the prepared statement of Mr. Moore.

Senator LUGAR. By unanimous consent, it will be made a part of the record. Please summarize.

Mr. MOORE. Senator, it has been about 2½ years since I was asked to leave the research environment in North Carolina and work toward the somewhat more controversial direction of management of the Pesticide Program as well as the Office of Toxic Substances.

My goals in trying to carry this out, I think, are fairly simple. Three things seem to stand out. One, that those decisions that we make in this highly technical area be scientifically sound. Two, we certainly would like to open up the process so that more people are aware of how to go about evaluating pesticides and also can be party to the process as we work our way through the system. Third, we have got to be timely in our decisions.

I think we have made progress in a number of areas. The controversial section 18 process for emergency registration of pesticides is again on sound footing. I think we have developed an aggressive ground water strategy which is in the process of being implemented. We reevaluated the criteria for special review in those instances where we have a particular concern over the possible adverse effects of pesticide use. We also developed inert strategies. Although the focus of most of the testimony that I think you are going to hear from me and others today is going to focus on old pesticides, I do not think we can lose sight of the fact that in the last 8 years, we have registered some 56 new pesticides. I bring that to the committee's attention because the data base for the registration of new pesticides is without parallel in the world for chemical toxicity data today. The condition of EPA's considering the registration of new pesticides is that all data must be thoroughly evaluated. And I think this applies to the chemicals that are now going to work in agriculture and elsewhere. I think it should not be lost that the new pesticides coming into use today are supported by a superior data base.

The current statute works. The deficiencies in the Office of Pesticide Program operations were corrected, or are being corrected by administrative remedies. However, I must also confess that the statute is cumbersome in many areas, and in the reauthorization effort, one should address possibly eliminating some of the encumbrances and should allow a more expedient process.

I am proud of the fact that we have in place a pesticide regulatory program that even its harshest critics concede has an emerging record of results. There is one issue, however, that casts a pall on the Agency's performance and continues to feed the public unease about the safety of pesticide use. This issue is reregistration of the older pesticides.

The prime concern is not how we are evaluating these products, but the pace of that process. Both the NACA/CPR coalition and the FIFRA coalition strongly identify with this issue, and have proposed, in different ways, to accelerate the reregistration process in the bills they have developed.

We at EPA applaud the fact that these groups and others with strong, contrasting views on FIFRA are taking a cooperative approach of identifying common issues and searching for effective remedies. However, until certain provisions are deleted, and others incorporated, we cannot fully support either of these bills.

The reregistration objective is a very simple one: The evaluation of each old pesticide using the health and safety criteria in the current statute.

While the process is straightforward, it becomes formidable due to considerations of scale. There are about 600 pesticide active ingredients subject to reregistration. So far, EPA has completed standards leading toward reregistration for about 127.

We invest large amounts of our own resources to identify gaps and inadequate studies. This process is very labor intensive. For example, to determine the adequacy of the existing data base for the approximately 429-odd active ingredients remaining at the end of fiscal year 1987, the Agency would have to review some 40,000 studies, which would require several hundred man-years just to go through with evaluation for accuracy.

We have been reevaluating whether or not this process must be done by the Agency. For a new chemical not yet on the market, the applicant seems to have no difficulty identifying, organizing, and submitting a complete data set to support that registration.

But one might ask why old chemicals are treated differently than these new chemicals; why should EPA be performing the preliminary work of organizing the data base on old chemicals which registrants can and do perform for new chemicals?

If we seek to accelerate the pace of reregistration, then let us conserve the Agency resources to focus on that part of the process that only it can do—evaluating data and determining the appropriateness of continued registration.

While S. 2215 would place the entire burden of identifying data gaps on EPA, H.R. 4513 and the Senate counterpart which was just introduced—I do not recall the number, Senator—place the initial burden on the registrants. This latter approach, with certain key modifications, provides a more equitable and cost-effective approach to identifying the data gaps.

Another issue, pesticides must have appropriate label directions and precautions to ensure that they are used safely, that the composition and packaging of the product are appropriate, and that any needed restrictions are in place. EPA may find—as part of reregistration or because of other review—that changes in labeling, packaging, and composition are needed to avoid unreasonable adverse effects.

Registrants usually comply voluntarily when the Agency seeks to impose such changes. However, in those instances where the registrant declines to comply with the terms of reregistration, the Agency is faced with a serious implementation problem under the language in the current statute. Ordinarily, we would impose these label changes through formal cancellation procedures under section 6. These procedures can be very costly as well as time consuming.

We think the Agency should have the option to use the more efficient rulemaking process to resolve these issues. While an extremely limited form of this concept appears in S. 2215, we believe that it should be explicitly acknowledged that the Agency be able to conduct rulemaking to require a wider range of changes to product registration, without having to go through the adjudicatory process.

Further, S. 2215 would allow labeling changes through informal rulemaking unless such changes would have a major economic impact. Since it could be argued that most label changes have such impacts, we recommend clarifying this provision.

Under the area of special review, in the midseventies, the Agency created the special review process, a rulemaking—like procedure designed to collect information, encourage public and industry participation, and assist the Agency in making a decision whether to commence cancellation proceedings.

Unfortunately, this overall process is very time consuming. Historically, the special review and cancellation of pesticide registrations under FIFRA have often taken more than 3 years, sometimes as much as 6 years.

The principal problem with the current cancellation system is that it consists of two processes; special reviews and formal adjudicative hearings, which repeat information gathering and decision functions.

Both bills quite correctly attempt to deal with this problem. However, the Agency is unequivocally opposed to the approach in S. 2215 resolving this issue. Certain features in the other bill, particularly the criteria for initiating special reviews, are more acceptable.

However, both bills leave the two-step process of special reviews followed by formal adjudications essentially unchanged, except for the incorporation of a series of deadlines.

Simply specifying short deadlines does not promote efficiency or provide the new procedures needed to allow EPA to meet these deadlines. Thus, adopting either bill would result in missed deadlines, poor decisionmaking, and unnecessary litigation.

I believe the intention of both coalitions to expedite the present review and cancellation process can be achieved by a more efficient means.

Right now, we conduct a special review proceeding that is essentially like an informal notice and comment rulemaking, except that it has no binding effect if a person adversely affected objects to the Agency decisions. If objections are made, we then conduct a formal adjudication, with witnesses and cross-examination, to actually make the decision. We think that combining the most useful features of both processes is the way to meet our mutual objectives.

We believe a hybrid proceeding which would add the benefits of cross-examination to the informal rulemaking process should be considered.

Since a hybrid procedure would combine the openness, efficiency, and speed of rulemaking with the opportunity for cross-examination, it would accelerate the process dramatically while still permitting detailed scrutiny of the important issues. We think this would make realistic deadlines attainable. We will, of course, continue to consult with our scientific advisory panel and with the U.S. Department of Agriculture, keeping them informed and involved in any process that would affect U.S. agriculture, as is currently done.

Proper regulations of inert ingredients is among the Agency's top priorities. Both bills propose the establishment of an inerts priority list of finite size, based on criteria designed to select those of greatest concern. We agree with this concept; limiting the size of the list enables the Agency to focus its attention on those substances that are most likely to cause health problems.

To summarize this area of inerts, the Agency is already implementing a comprehensive strategy to deal with inerts. The Agency would benefit from legislative clarification of our authority to list certain inerts on product labels and to require data necessary to evaluate them. To focus Agency attention on the critical issues, we favor limiting the size of the list of inerts. These legislative changes coupled with administrative improvements already implemented will effectively deal with the inerts.

Dealing with the issue of certification and training, the abilities to classify a pesticide for restricted use and to prescribe limitations on its use via the label are essential regulatory tools. For this system to work well, however, applicators and those whom they supervise must have a high level of competence. Thus, one of the Agency's chief objectives, shared by USDA and our State colleagues, is to further develop and ensure a level of professionalism in certified applicators and those whom they supervise.

Senator, I had a task force last summer that looked at this issue and came up with a series of recommendations. Also, the Agency had an Administrative Pesticide Advisory Committee that discussed this issue among other things. But there was one area of consensus with both of these groups, and it was that we need to have a better opportunity to demonstrate proper education and knowledge as to the use of pesticides, particularly to those that may have potential for serious and adverse effects.

They identified a number of issues that they feel will allow us to realize this goal. I have summarized these in my testimony, but let me highlight a couple.

First, Congress should give EPA the flexibility to specify the appropriate level of supervision a certified applicator must exercise in the application of a restricted use pesticide.

Also, Congress should provide a mechanism authorizing EPA and the States to enhance the level of competence of persons who work under the supervision of certified applicators.

Third, Congress should remove the prohibition in section 4 of FIFRA which forbids EPA from requiring the examination of private applicators after training in order to establish competence.

Fourth, Congress should authorize the establishment of State pesticide dealer licensing programs.

In the area of penalties, we think that the current provisions in FIFRA clearly need to be updated. The present penalties lack significant deterrent value. For example, had the Agency been responsible for enforcing the recent pesticide incident in California last summer, involving the misuse of aldicarb on watermelons, the maximum civil action possible under the current statute would have been a warning notice to the applicators. You will recall that dozens of our citizens sought medical treatment as a result of this incident.

In the area of indemnity and disposal funding, we think that contrary to all other regulatory statutes, current law provides in sections 15 and 19 that if a product is suspended and canceled, EPA must both indemnify the owner of the pesticide for losses and accept the pesticide for disposal at Federal expense.

Manufacturers, not the taxpayer, should absorb the cost of needed recalls. The Agency wants this legislative requirement for Federal liability stricken from the statute.

There is also considerable sentiment for having registrants pay the costs of the pesticide program, and we are exploring ways to recover these costs. We believe that users should pay for services provided them. Explicit legislative authority to recover registration and reregistration costs annually is being sought.

There is also an EPA-wide effort to identify and evaluate potential fees for the services the Agency provides. There are important questions about allocation of fee revenues, the activities subject to such fees, and the use of fees as policy tools rather than simply as revenue sources only.

We believe that your consideration of such questions could be extremely helpful, and are anxious to work with the committee to develop language for the FIFRA authorizing a fee structure that would recover full program costs.

Senator, I have a number of other items that are in my testimony that I will not highlight, and I will just summarize by saying we think the most important pesticide issues before us are efficiency in the reregistration process and special review programs, effective regulation of inerts, competency of certified pesticide applicators, adequate enforcement responsibility, and realistic fee structures for the pesticide regulatory activities that must be performed by the Agency.

While we are pleased that both bills focus on these issues, we believe that the Agency's alternative proposals outlined in our testimony would achieve our shared goals much more effectively.

With these comments, I am concluding my prepared statement, Senator. I am hopeful with this constructive start, that we will have a fruitful legislative process in 1986.

I will be glad to answer your questions.

Senator LUGAR. Thank you very much, Mr. Moore.

Let the Chair note the distinguished ranking member of the committee, Senator Ed Zorinsky of Nebraska, has joined us during your testimony; and Senator Pat Leahy of Vermont who, as chairman of the Subcommittee on General Legislation and Research, worked with me as the junior partner of that enterprise as ranking member in 1978 for reauthorization.

Senator LEAHY. I think we worked on that for about 40 years.

Senator LUGAR. Yes, for at least that long, and not much has occurred since. [Laughter.]

But in any event, we are optimistic about the procedures this year, given the good will of all the participants. Let me begin again by asking Senator Zorinsky if you have questions of the witness at this point.

Senator ZORINSKY. Mr. Chairman, I have no questions. However, I have an opening statement, and in the interest of time, I ask that the statement be made a part of the record.[3]

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[3] See p. 123 for the prepared statement of Senator Zorinsky.

Senator **Lugar**. By unanimous consent, it will be inserted in the record. Thank you.

Senator Leahy, would you like to proceed?

Senator **Leahy**. I will also submit a statement for the record, if I could, Mr. Chairman. The statement supports S. 2215, the bill that I have joined you and Senator Proxmire in introducing.[4]

Mr. Moore, in the prepared text, I found some constructive criticisms of S. 2215, the bill that I introduced along with Senators Lugar and Proxmire. But, why hasn't the EPA sent the committee a request bill that might cover these concerns? Why doesn't the EPA, if the Agency has these concerns, just draft a bill itself, send it to the committee, and have it introduced by request?

Mr. **Moore**. Senator, our feeling was that given that there had been months of effort invested by various parties who typically have polarized opinions on this, we felt it might be more appropriate to try to work from the activities that they have identified and put together in the bill which you introduced, rather than create yet a third or fourth bill, depending on how one counts.

So that is what we did.

Senator **Leahy**. Well, of course, the issues addressed in our bill have been discussed for years by environmentalists, by manufacturers, and by agribusiness. Senator Lugar talked about many of these issues back in 1978--I think we have probably had more extensive hearings on this than any single issue that I can recall in 12 years. I have served on the Agriculture Committee I guess longer than anybody other than Senator Helms and Senator Dole, and I cannot recall an issue that we have spent more time on.

I would certainly welcome any effort you might make to work on FIFRA with us. Your statement also seemed to indicate that your resources are nearly committed. With the current budget you face, are you going to actually be able to work to improve pesticide monitoring and registration?

Mr. **Moore**. Senator, as you well know, both bills identify a process which is an accelerated process. The reregistration of pesticides is also a labor-intensive effort. So any time one proposes to accelerate the process without making very significant changes in how one goes about doing it, implies an increased need for resources.

While we certainly are not averse to seeing this reregistration issue behind us, I think it is also quite clear that if we are going to accelerate the process, there must be enough revenue generated as part of this change to be commensurate with the increased demands which will be placed on the Agency to realize this goal.

Senator **Leahy**. Well, I think when Senator Lugar and I first wrote part of this legislation, we set as a goal to have only safe pesticides in the environment. We did not intend to suddenly slam the door and said there could never be new pesticides. We wanted to establish a balance, to make sure there are safe pesticides, yet allow the normal advances of science to go on.

I would look foward to whatever suggestions you might want to make. I do not want to speak for the chairman, but I do not think anybody has their feet in concrete on compromise. We want a program that is going to work, and be able to reflect the advances in science, but also have safe pesticides. We want to make sure that whatever reregistration procedure we set up is a clear one, yet one that moves with at least all due speed as well.

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[4] See p. 125 for the prepared statement of Senator Leahy.

So I would invite you or your staff to work with me in any way you can. I think the need for progress in reregistration is pressing, and I think you will find in this committee many people who are very concerned. Many of us are knowledgeable in this area and do want to work with you.

Mr. MOORE. Senator, I certainly look forward to working with you.

The Agency did impose one burden upon itself, which I think we have kept faith with so far, and that is that as we reviewed other various statutory initiatives and found something that we found to be not totally satisfactory, we laid upon ourselves the requirement that in addition to identifying that which we did not think was most effective, to identify what we thought would be a more effective solution and to articulate it. We still intend to hold to that.

Senator LEAHY. Thank you very much.

Thank you, Mr. Chairman.

Senator LUGAR. Thank you, Senator.

We have been joined by the distinguished Senator from Alabama, Howell Heflin, and the Senator from Kentucky, Mitch McConnell.

Senator Heflin, do you have any opening statement or comments at this time?

Senator HEFLIN. No. I am just here to learn and listen.

Senator LUGAR. Very well.

Senator McConnell.

Senator MCCONNELL. I do have an opening statement, Mr. Chairman, that I would like to have put in the record.[5]

Senator LUGAR. By unanimous consent, it will be made a part of the record.

Senator MCCONNELL. Thank you. I have no questions at this time.

Senator LUGAR. Mr. Moore, for the sake of the hearing record, I would like to raise a number of questions. Some of these you may have testified upon, both in your oral testimony today and likewise in your more comprehensive statement.

Let me ask first of all, if you had to choose as a markup vehicle between the NACA/CPR and the CMSA bill, which proposal for reregistration of old pesticides is more workable for EPA? And can you create a fee schedule for reregistration that would be more equitable to small producers to protect the interests of minor-use crops?

Let me ask that from the standpoint not of attempting to put you into an impossible bind before you even start the process, but to indicate that the so-called compromise bill that Senator Leahy and I are involved with, and we have offered to get the ball rolling, and Senator Helms has suggested legislation that is favored by many of the smaller producers, and also the American Farm

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[5] See p. 127 for the prepared statement of Senator McConnell

Bureau, because of special problems that they perceive. I believe they are taking an up-front look now at this reregistration process as something that is tremendously important and on which we really need your input as to if you do not produce a bill of your own, where do we start?

Mr. MOORE. Senator, we have not had the opportunity to review the bill that Senator Helms has introduced in as much detail as we have the NACA/CPR bill, so I am not sure that I am in a position to say which would be the preferred instrument for markup.

I do note that indeed the bill that has been more recently introduced by Senator Helms is much more broader in scope in that it speaks to a number of issues beyond that which are in the NACA/CPR bill. On the other hand, I think in the NACA/CPR bill, when they identify an issue, they often in my personal opinion, have gone into it in much greater depth.

So I think, in a way, it might be a boon to both.

Senator LUGAR. Perhaps we could keep the record open for a while, and you might examine that situation. Senator Leahy has invited you to make comment on that, and that would be very helpful, I think, to all of us, because your expert testimony is important, and we appreciate that you have not had an opportunity to give full study to the most recent submission; and that would be important so that we can get off on the right start.

Now, in the reregistration picture, in your judgment are changes in the statute necessary? You have proceeded to mention the very great burdens to EPA as you now proceed, and you have cautioned against timetables that are too tight.

Is it your judgment that we ought to make changes in the law, or is this reregistration area one that you can handle with flexibility in a current statute? What is your general judgment on that?

Mr. MOORE. Senator, one of the problems with the old pesticide and reregistration process, we cannot lose sight of the fact that based on our experience to date that somewhere around 20 percent of those chemicals in the reregistration process are triggered into the special review process because of a particular concern of one sort or another.

Senator LUGAR. One hundred percent?

Mr. MOORE. Twenty percent, give or take; it varies, obviously, from year to year.

So the special review process does take a significant amount of time and also is focused on those chemicals that should be of priority concern to the Agency. Our sense is that the process that we currently follow, while the final result may be a lesser result, there has just got to be a better way of doing something, rather than go through this process of special review which, if contentious in its outcome, then goes into an adjudicatory hearing which then lasts several years, and basically, is conducted as if the present review process never existed. To me, this seems to be a waste of resources of the Agency as well as others.

We certainly would like to see a change made. The problems that we have had with the suggestions that have been made in both bills speaks to the fact that they would like to see the process accelerated—in fact, they identify time lines, in some instances—but they in essence have imposed time lines without making any material changes in the system itself. And expecting the motor just to rev up and go faster, and then by that process become more efficient, we just think is not going to work.

If you are going to materially shorten the historic process, you have got to change the way one does it.

Senator LUGAR. All right. You made some comment today about, at least philosophically, how the system might be changed. I think you understand the problem that most Americans see in this, because you mentioned this morning that work on 127 standards has been completed, but that 420 active ingredients remain at the end of fiscal 1987, and 40,000 studies which the Agency would have to review in order to come to proper judgment.

Just for the sake of the record and for laypersons who are trying to follow all of this, how did you begin to identify that there were approximately 600 ingredients out there that needed to be examined? And of the 127, are these the ones that have enormous application, or is it a narrow field? In other words, did you pick the 127 that seemed to be the most important, or at what point do you select specific ingredients to examine?

Mr. MOORE. Well, Senator, the total universe is around 600 active ingredients. Basically, we identified those pesticides that were registered prior to 1978. That was roughly our cutoff.

Senator LUGAR. So you have a list of those that are fairly certain, and that is the universe.

Mr. MOORE. The 127 that we have worked on were not drawn by random lot out of this universe of 600, but indeed were addressed according to a priority scheme, which put a priority on those chemicals that are primarily food use pesticides, and also implicit in their use represent a fair amount of public exposure to those chemicals. So the ones that we have done, I would say represent the more important pesticides from the standpoint of possibility of adverse impact on the part of someone who is exposed to them, should we in the process of reregistration identify concerns that we did not know heretofore.

Senator LUGAR. Fine.

Mr. MOORE. Senator, I might also point out for those who are not aware of it that when I talk about 600 to 127, I am talking about active ingredients. There are up to 40,000 to 50,000 registrations that are involved.

Senator LUGAR. Yes; combinations of these ingredients.

Mr. MOORE. Yes.

Senator LUGAR. Are you suggesting to narrow this 420, that there must be changes in the system, that simply changing the deadline will not make it: you will not be able to make the deadlines, and there will be frustration with regard to the law.

Outline again the changes in the system that you are recommending, and are you in a position to try to phrase this in legislative language, or do either of the two bills that have been introduced pick up any elements of these new systems that you would suggest?

Mr. MOORE. One of the systems that I alluded to earlier was this cancellation proceeding, or special review proceeding, which we think needs to be changed to accelerate that part of the process.

That would affect probably 20 percent of the active ingredients that are under consideration.

The other area that we think one could benefit by changes from that which has been proposed is that in the process that we are in right now, we have old data in the files. Somebody has to go through that data to find out whether or not, by current standards, it is adequate for the purpose for which we would like to put it to use. And indeed, as I identified, this is a labor-intensive process, not necessarily a terribly difficult process, it would seem to me, and in order for the Agency to do this, we are talking about several hundreds of man-years. This is strictly to go through the data to find out whether it is adequate or inadequate, and not to analyze the data for possible adverse health or environmental effects.

This in essence has to be done before one can identify what new data has to come in in order to evaluate and also to be able to render judgment on reregistration of one of these active ingredients.

We would hope that indeed the burden for this activity would be to review the data, reformat the data, which would allow the ease and efficiency of our analysis of such data, could and should be done possibly by the registrant. The reason for saying that is that there are a lot more registrants than there are EPA's, and that indeed, one is laying off this large data requirement to a number of companies and individuals to do it, and hopefully the Agency can then take the resources that it would have had to spend on this effort and invest them in areas that only it can do, and that would be evaluation of data that is coming in as part of the reregistration process.

Senator LUGAR. In a practical way, how would this work? In other words, you are suggesting that registrants would bear that burden. This means that specific chemical companies that have an interest in this process—how would you assign those burdens? Is it clear—who ought to undertake any and all of the 420? Would you be able to make sort of a clear path of responsibility for all of them?

Mr. MOORE. Senator, in the last couple years, we have identified test guidelines as well as test data requirements for pesticides in various uses. Using that as a framework, I think, in going to a reregistration process, somebody can consult that type of information that is available and determine that which has never been submitted, because at the time of the original registration, it was not a requirement, for example; or can, in maybe a more tedious fashion, look at the old data that it might have submitted as to adequacy. We would suggest that the current registrant should have to only submit to reregistration—say that their intention is to reregister CP registration, and in the process of doing that, identify and commit to the filling of a clear data gap. Then maybe 6 months or 8 months after that, they should then come back into the Agency and give us a summary of all the data that they think is already in our files in support of reregistration that they feel is adequate. The Agency then would review that material, and then set a time definite to when registration would expire, based on the leadtime that would be required to fill in the data that is currently missing. Then, once the data is in, we evaluate such data to determine that indeed there is no unreasonable adverse effect and issue a continued registration with any needed changes as is appropriate and, in those 20 percent of the instances, enter into a special review process where there is an unreasonable adverse effect that needs greater degree of scrutiny.

The processes have identified that, as has been described by some, there is somewhat of a barbell to our data requirements. There is a large manpower requirement upfront, to review all of these old studies as to adequacy. Then one goes into somewhat of a reduced labor demand while this data is being generated, and then of course, 7 years out, you then have all this data coming into the Agency, and then you have this large amount remaining.

What we would like to do is to identify a process whereby we can even this out a little bit. One of the ways to do that is to have this front-end labor requirement, being borne to some greater degree by the registrants themselves.

Senator Lugar. Let me ask, do you have an estimate as to how many of the 420 ingredients would fall by the wayside and that the registrants would decide not to pursue for reregistration?

Mr. Moore. I do not have an accurate figure. Two figures come to mind. We did a review last year of slimicides and turf insecticides. The results of that were carried into some of the other uses. We lost roughly one-third, even a little better than one-third, of these chemicals. That is, once the person who held the current license or registration was notified that they had to commit to replacing the missing data, they either wrote back stating that they would not commit to filling these gaps, or failed to write back to the Agency and so they have been suspended and ultimately canceled.

Whether that would hold true in the other remaining 400 out there, I am not sure. Our experience in 350-odd active ingredients that are food use pesticides was that we lost around 50 of those materials as we went through this process. What we have done with those is informed the registrants and made them commit to vacancies in their files—like we required two studies to assess carcinogenicity or cancer-causing potential, and there is only one in the file; the commitment to fill in that one is a $500,000 to $700,000 commitment on the part of the registrant. So, clearly, that would indicate to us that when one commits to doing such a study, their intent is to maintain that reregistration, even if we come subsequently and identify other data gaps that also need to be filled.

Senator Lugar. All right. Have your thoughts with regard to asking registrants to undertake this burden been conveyed to registrants in preparation for these hearings or for this legislation reauthorization, and what is their reaction?

Mr. Moore. We have had active discussions in the last few weeks with a number of parties who are interested in this, and they are giving very serious consideration as to what could be done on their part toward evening out this total role, and it would be up to them to articulate where they want to finally come out on this.

Senator Lugar. Obviously, one of the tradeoffs—I do not want to identify all of them, because we have many witnesses—but we have a situation here in which you have gotten to 127; you have 420 to go. Regardless of what type of a law we pass, it is clear to you that there are going to be problems with simply squeezing deadlines for our own anxiety. So you are suggesting, as I understand it, really a very different kind of system. And it depends upon, I suppose, the self-interest of the registrants and the various other witnesses in our society who will be heard, as to whether they feel that is a good idea, whether the costs or burdens they are undertaking offset the time problems and general uncertainties that are now in process.

This is why I so tediously wanted to explore this part of it, because I think the reregistration issue is one of the most important ones that we have to take a look at, and I think you can be sort of wrestling with that, whichever draft we happen to undertake.

Do you favor any changes in the present regulations concerning conditional registration—and I mention this because the EPA has received many criticisms in this area in the past and what have you been doing to correct the problem or meet the criticisms?

Mr. Moore. Senator, we issued, just in the last few months, a statement that identifies what our policy is as to conditional registration. So we are very comfortable with that policy and do not necessarily see any need for statutory changes in that area.

Senator Lugar. What do you feel with regard to the issue of false or invalid data, and have you issued new regulations on this recently, or do you have any comment on either of the two draft bills as it pertains to that issue?

Mr. Moore. Senator, we put out I guess it was 2 years ago, "Good Laboratory Practice Regulations", which articulates what procedures we would like to have followed in order to ensure that once a study was done, that indeed the data would be held to be accurate and worth consideration by the Agency.

What we would see if we need is—our interpretation of the statute as it is currently is that with one exception, a violation of a regulation we would promulgate on FIFRA is not identified as a violation of the statute, and as a result, we have no penalty problems. So although we have no GLP regulations in place, for example, if one wanted to move against somebody who failed to comply with that, we feel that under current statute, we could not seek penalties against them. We would like, certainly, to see that changed.

Senator Lugar. What proposals do you favor regarding the regulation of inert ingredients? I ask this because I wonder if the Agency can realistically deal with 1,200 inert ingredients under the current system that you have.

Mr. Moore. Senator, we put a process together about 1 year ago which identified how we would go through an evaluation of those 1,200 inerts, and we basically broke them down into several categories. One category, you have got to have "safe chemicals" and things of that sort—a couple of hundred chemicals are in that category.

On the opposite end of the spectrum, we also identify about 50 chemicals in which we had data in hand which would suggest to us real potential for adverse effects. And behind that was another group of chemicals on which we had less data in hand, but based on analogy with other chemicals that we do know something about, we would be suspicious that indeed they may also pose a toxic problem. We then have this large area in the middle, of roughly 700, that we basically would simply say we have no reason to believe that they should be of particular concern for adverse effects, but we also could not sit here and say they are grasslike materials at this time, either.

The focus is on those first two categories. The category in which we think we have data in hand suggesting adverse effects. We have been working with the registrants to see how many of these materials might be in the current files, and our sense has been to date that in most instances, many of the registrants voluntarily are committed to move away from the use of those inert materials.

So our focus is on the front end of the materials. The second category of chemicals in which we have reason to be concerned, but lack definitive data and would like to move on those as a priority—this is where we do support the approach in both bills that, indeed, one should have a finite list out of this universal 1,200 that should be a focus of attention, rather than divert us by trying to look at 1,200 all at once. So, a list of finite size we find to be of value.

They both go into the mechanism whereby the chemicals of this priority concern on the list should be evaluated and comment taken before we require data. We find that this is much more cumbersome than it need be. Our sense is that the requirements that are being asked in those statutes are much more than one currently has to go through for an active ingredient. So we think they might be getting a little out of sequence.

Senator **Lugar**. Do you have a specific review list for inert ingredients?

Mr. **Moore**. Yes. We came up with criteria for review; we then came up with these different lists. We consulted our scientific advisory panel in both the criteria that we used as well as the data required and we do have a list—we actually have four lists.

Senator **Lugar**. Does the panel or someone else in your Agency make a risk assessment of each of these?

Mr. **Moore**. Yes; our lists were put together based on hazard alone. That would be that we have data in hand that suggests that there may be an adverse effect based on experimental results. It did not lay on the other major piece required in doing a risk assessment, and that is the amount of exposure that might be associated with that inert's use in a particular formulation. We are in the process of looking at that to identify those conditions whereby the particular inert, while it might have hazard potential, also represents sufficient exposure to be of a risk concern, and are moving through it in that fashion. We do identify, for example, some of these inerts which, while clearly hazardous, pose no risk in certain circumstances, because human exposure or environmental exposure is simply nonexistent.

Senator **Lugar**. Let me break into this series of questions to recognize that the distinguished Senator from Montana, Senator John Melcher, has joined us.

John, do you have an opening statement, or opening contribution to the hearing this morning?

Senator **Melcher**. No; I have no opening statement, Mr. Chairman. I am pleased, though, that we have started on the hearing process.

This has always been a difficult area to arrive at proper legislation, so it is needed again now, and I am glad we are starting.

Thank you.

Senator LUGAR. Thank you, John.

Let me ask you, Mr. Moore, can you briefly explain what you perceive to be the differences between the two legislative proposals on cancellation procedures; and very specifically, are your November 27, 1985, regulations or cancellation procedures performing as expected?

Mr. MOORE. One of the basic differences between the two is the criteria or triggers, if you will, that would push something into the special review process. One bill identifies it to be on the basis of hazard alone; the other one does it more on a function of exposure or risk.

As I mentioned in my testimony, we recently have revised our regulations or criteria by which something went into special review, and moved from a hazard-only to a risk-driven trigger. We think going back to a hazard-driven trigger right now would be going backward and would be counterproductive. What it does is that it forces more things into the special review process which should be of priority concern, and in fact, may put some things in there, in broad focus of EPA, USDA, as well as others, on issues that clearly do not need that focus.

Another thing I think we need to realize is what the special review process does from the public perception standpoint. The public, I think, clearly would identify that the Agency is taking chemical rights and putting them into special review because of a particular concern, whether it be birth defects, cancer, or some environmental effect. And they rightly, I think, would focus on that, "Well, now, what is the Agency going to do?" I think that if we put things in there that do not belong there, we are sending the wrong signals to the public.

The other thing I think that happens is if you put something in there on the basis of hazard alone, we are going to have to wait a growing season or two growing seasons in order to get sufficient data to reach a determined judgment. The public can become skeptical. You said that this was a major concern, and you put it in there, and the language is for years. I think we should not lose sight of that fact, as well.

Senator LUGAR. Why is it necessary for the EPA to inspect the laboratories? Do you feel you presently have adequate authority to inspect these facilities? Do you favor either of the legislative proposals in this regard?

Mr. MOORE. We currently do not have authority to inspect the laboratories if someone does not care to let us in. We currently, in some instances, gain entry by going with our colleagues at FDA, who do have that authority.

Senator LUGAR. Do you believe that pesticide users should be exempt from liability if they have adhered to label instructions?

Mr. MOORE. Senator, I think actually, the whole issue of liability from an insurance standpoint is something that has plagued us all in a variety of circumstances, and pesticides certainly are no exceptions. I think the need for change in that area should be done under the evaluation of liability in general and not just use of pesticides, as an example.

On the other hand, I do think it would make sense if one were going to do something to somehow maybe, instead of putting ceilings or limits or whatever the case may be on something of that sort, if indeed one could demonstrate that the person who was involved in the application of that material was well trained, was objectively tested to ensure that they did have proper knowledge, and then had reason to believe that they applied the material according to the best methods available, best information available. We do not currently have that system in place.

Senator LUGAR. Let me touch upon another general subject that has been debated for some time. Should local authorities be precluded from regulating the sale and use of pesticides within their local jurisdictions?

Mr. MOORE. Senator, that is an area that the Agency has and continues to remain neutral on. We think that is an issue between the States and the local jurisdictions.

Senator LUGAR. Is the current law with regard to data compensation performing satisfactorily, and are you recommending any changes in that area?

Mr. MOORE. As far as we are concerned, no changes.

Senator LUGAR. What is the total cost of the pesticide program under current law, and what impact would either of the two bills have on that total cost, and in the event that there is additional cost, how do you expect to get the resources to do the job?

Mr. MOORE. Senator, if my memory serves me correctly, current operations of the pesticide program itself is around $60 million a year. Our estimate is that that would have to double, higher than that, to go into some of these barbell phases that are implicit in a couple of the bills that have been identified.

I think our position is clear, and that is, if one wants to accelerate the process, additional resources are going to be required, and any statutory change that is going to accelerate the process has also got to find a mechanism whereby resources do not have to be commissioned piecemeal.

Senator LUGAR. So you almost turn full circle to the first question. If you are suggesting that you currently have a budget of $60 million annually, and you think that might become $120 million if these procedures were enacted, you are suggesting that as opposed to going to $120 million, the incidence of burden go to registrants, so that apparently, a portion of that $60 million would go to those who are in the field out there, wanting these registrations.

Now, do you expect that in the total sum public good that the registrants would be able to provide these services for less than $60 million—in other words, would the total pie in terms of costs diminish if private people did the portion of the procedure you are suggesting?

Mr. MOORE. Senator, I think streamlining the process whereby we can be much more efficient in what we do, would certainly have some impact. But I think a great impact would be realized by removing from the Agency the requirement for going through these 40,000-odd studies in a labor-intensive fashion, and put that burden back on the registrants. Obviously, it would decrease our workload in that area and the costs that would be identified by EPA would go down proportionately.

Senator LUGAR. Obviously, this is a critical area of our consideration, and I would ask again that you work with the committee and others, for that matter, in language that expresses at least your optimum point of view—and this is going to be messaged by all the parties in this situation, but I think it would be well to at least start out from the standpoint of your consideration today, and your testimony has been very helpful.

Senator Heflin, do you have questions for Mr. Moore?

Senator HEFLIN. This bill that Senator Proxmire and Senator Leahy and whoever the other author introduced—Lugar, I believe. [Laughter.]

This bill, as I gather, has gone through a rather thorough discussion between various environmental, labor, consumer organizations, as well as the national agricultural chemical groups and farm groups. The bill is basically the consensus of all of these groups, which is pretty remarkable to get them all together.

There are some, of course, including some farm groups and small chemical groups that have differences on such things as the minor crops.

Do you have any comments that you might want to make as to how, if this bill were to be adopted, you would deal with that, and whether there is any answer to their concern?

Mr. MOORE. Senator, let me start out by saying that I certainly think that all of the issues that were identified by the NACA/CPR group are legitimate issues and are the correct things to focus on; and indeed, the goals that they have identified, I think we are in basic agreement with. If there is any difference between us and the goals, it may be the roadmap sometimes that they have identified that we are going to have to drive in order to get there; we might suggest an alternative route, which I have tried to do in some of my testimony.

In relation to the minor use issue, our sense thus far has been that we have not realized any major loss of pesticide availability to some of the minor use crops. Our basis for that is that in almost every instance, the use of a pesticide for a minor crop is always tagged onto a use of that pesticide for a major crop, and that indeed, as we have gone through this reregistration process and the commitment for data to support that reregistration, the normal circumstance has been that the company did commit to providing that data, knowing that the economics associated with major use crops, the public could sustain that.

The burden, then, that is left on a minor use for that particular crop becomes, I think, relatively small. Our data suggests that we have not seen many minor uses in a lot of the reregistration process today. I can provide you with some facts and figures on that, Senator.

Senator HEFLIN. One of the concerns of some of the farm groups is that this will end up in the removal of a great number of products from the marketplace, leaving the farmer without adequate means to protect crop investments in the land. Sometimes, looking back over the history, we have had some problems where EPA has removed certain chemicals. We have had a big problem particularly in the South with the fire ants. It seems like EPA is forever looking into this matter, and we cannot seem to come up with anything to adequately take into account the problems created by this.

Now, what sort of safeguards would you undertake to follow where there is merely a scintilla of question about the health hazard of this as compared to its relative use to the farmers. We have gone through this with the Food and Drug Administration with saccharin; we have gone through it on so many things, and find that you have to feed 30 soft drinks a day with saccharin in it before it would cause even any appearance of cancer in a rat, or something like that. They have got some extreme examples on this.

It seems to me that if this is adopted, that there ought to be some safeguards set forth from a regulatory agency in the removal of products, where it leaves the farmer without adequate replacement. There ought to be some standard of proof that it is going to cause, or is likely to cause, damage to the public and to the health and removal. This can be a big problem, and I just wonder if you have any comments as to how this might work and what safeguards we might attempt to develop on the question of removal of crops?

Mr. Moore. Senator, I cannot lose sight of the fact—as you were speaking, what came to mind was that the FIFRA statute is a risk benefit statute, and we must, by law, in addition to considering risks that might be associated with the use of a particular pesticide, we must also factor in the true benefits that are derived from the use of that material. Also, as the statute is written, as we are looking toward possibly moving against a pesticide for a particular use because we think there might be an unreasonable risk associated with that, we must, by statutory requirement, consult with the U.S. Department of Agriculture and consider and factor what comments they may have before we make a final decision. Our experience has been that USDA typically will come forward with a fairly well-articulated case as it relates to the two benefits that might be associated with the use of the material. I think that is all to the good in making, hopefully, the final reasoned determination on an evenhanded basis.

In relation to minor use, the comments I made earlier are primarily prefacing toward the food crops. There might be an adverse fallout for some of the nonfood minor uses of materials. What comes to mind are, say, things used on ornamentals or things that are used as disinfectants, where you do not have the economic base of a major use to enable you to underwrite some of the expenses that are possibly involved.

In relation to fire ants, I am told by my colleague that we do have a new product coming onto the market that I am told holds some hope for that.

Senator Heflin. Well, they better get it in a hurry, or we are going to be submerged by them.

Now, there is some issue about whether or not local governments have any authority, or whether this is strictly a State and Federal preemption of local government authority to regulate pesticides.

Mr. Moore. Senator, the current statute requires EPA to set a base of a minimum that it might have associated with the use of particular pesticides. It then leaves to the States the opportunity to indeed become more restrictive as to that particular use, including maybe outright saying they would not allow that use.

The Agency has remained, and I think will continue to remain silent as to whether or not that primacy should stop at the State level or whether one should allow the lower political subdivisions of a State, whether it be county or municipality, to indeed also have further restrictions on pesticide use beyond that which was laid on by the State.

That is a political thicket that I think it would be wise to try to leave to the States and their municipalities. It certainly is a strong issue in some parts of the country.

Senator HEFLIN. I believe that is all.

Senator LUGAR. Thank you very much, Senator Heflin.

Senator Heflin has succeeded in getting the fire ants back into the hearings. And hopefully, some success will occur during our——

Senator HEFLIN. Or I will bring some up here. [Laughter.]

Senator LUGAR. There you are. That would stimulate consideration.

Senator Melcher, do you have questions for the witness?

Senator MELCHER. Mr. Moore, are you familiar with the Burmeister report on the incidence of cancer in Iowa farmers?

Mr. MOORE. Not by that name, Senator. Is this one that alludes to an increase——

Senator MELCHER. I am not familiar with it myself. I understand that Burmeister reported in 1982 that cancer mortality in Iowa farmers during the seventies was higher than urban dwellers in Iowa, and that it was not related to smoking. I do not know how that ties into pesticides, and I was hoping to get a little instruction on this, so I will get that from somebody else. Maybe I will get ahold of the study myself.

In regard to EPA's authority on exporting of what has been determined as a hazardous chemical, how is that addressed right now under existing law?

Mr. SCHATZOW. We have under section 17, Senator Melcher, provisions for notification, and for a pesticide which has been canceled in this country, if it is exported abroad, there has to be prior notification to the country of import that it has been canceled in this country and the reasons for the cancellation.

We have been working under the auspices of the United Nations with both European countries and the Third World countries in order to assure a proper system of notification and who gets these notifications, so that the people who would be importing these products do clearly understand that they have been canceled in this country and why they have been canceled.

Senator MELCHER. When did we adopt section 17? I suppose we modified it a couple of times. Was it revisited the last time——

Mr. SCHATZOW. I believe it was adopted in 1972 and modified in 1978.

Senator MELCHER. That is about 14 years ago. Can you give me a for-instance of something we canceled here in the United States because it was extremely hazardous, and what happened?

Mr. SCHATZOW. Do you mean the extent of usage abroad; is that the question?

Senator **MELCHER**. My question is simply this: Has EPA canceled some rather hazardous chemical on which the inventory was then dumped abroad?

Mr. **SCHATZOW**. I do not know the extent to which we have that information. I would be happy to try to respond for the record.

Senator **MELCHER**. How many have you canceled?

Mr. **SCHATZOW**. Well, we have canceled a variety of chemicals and a variety of uses—DDT, Aldrin, Dieldrin, Heptachlor-chlorodane—most of the uses of those chemicals have been canceled—Endrin, Solex, 2,4,5-T. I would be happy to try to pursue that for the record in terms of trying to gather whatever data we have as to what the extent of exports has been subsequent to the cancellation.

Senator **MELCHER**. A number of those are hydrocarbons which have been found to be hazardous in that they cause cancer. Has there been any significant amount of inventory that was cleared out simply by selling it abroad after it was canceled for use here in the United States?

Mr. **SCHATZOW**. Senator, I would be happy to provide that for the record to the extent we have that information.[6]

Senator **MELCHER**. Do you have it?

Mr. **SCHATZOW**. I am not sure. I am not sure of the extent to which we do have it.

Senator **MELCHER**. I am not sure we can make much headway on the policy you are recommending if we do not know what the extent of the problem is.

You say both bills propose "a significant and unnecessarily complex expansion of the export notification system and they would far exceed those required in the FAO International Code of Conduct on the distribution and use of pesticides."

Aren't we the leading country in developing and using pesticides?

Mr. **SCHATZOW**. I believe that is correct.

Senator **MELCHER**. Therefore we are going to be the leading country in realizing the hazards involved in the use of a hazardous chemical. So, aren't we always going to be ahead of the FAO International Code of Conduct?

Mr. **SCHATZOW**. Well, the FAO International Code of Conduct is a mechanism for communication. The actual analysis of different chemicals, although the United States is also in the lead, a variety of the European countries and Japan also have active programs for the investigation of many of these pesticides, and we work together internationally in coming up with these——.

Senator **MELCHER**. Are any of these pesticides sold to Third World countries who have not only no knowledge but also no method of examination, no method of analysis, no method of describing or evaluating the seriousness of the hazard themselves?

Mr. **SCHATZOW**. I think it is fair to say that the level of sophistication in many of those countries is far less than it is, obviously, in this country and the European countries. And that is, again, where the notion comes from of the kind of notification that says let us make it very clear to those countries when those types of chemicals are exported abroad, what kind of data we do have; the fact that if we did cancel the chemical, why it was canceled, and what the rationale was.

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[6] The material furnished by Mr. Schatzow in answer to the questions from Senator Melcher was too voluminous for reprinting and has been retained in the committee files.

I think the other part of the theory behind the existing statute is that when we are dealing with a risk benefit statute, as this is, as opposed to a statute which has some notion of absolute safety, but which recognizes that there are certain risks and that there are certain benefits, I think the notion of the existing provision is that any country may balance those differently, and that what are of limited benefit in this country may be of greater benefits in other countries.

Senator MELCHER. Does it also serve our self-interest in that, for instance, DDT is still allowed on vegetables in Mexico?

Mr. SCHATZOW. I do not believe in Mexico—it is allowed—there are uses of DDT that are allowed in other countries.

Senator MELCHER. Far be it from me to want to see you burdened with a complicated system of notification, but nevertheless, there are two aspects of this. If it is hazardous, and it is exported to a country, that is bad for them. But also, if it happens to be a country from which we import the strawberries and the lettuce or what-have-you, such as Mexico, it is bad for our consumers. We may clean up the producers here and then find out we are getting it back in spades simply because we allow the importation of those products.

Mr. SCHATZOW. Yes; we are going through a process which we are about halfway through in which we are canceling the tolerances of all chemicals, revoking the tolerances of all chemicals that have been canceled in this country. What that means is that any commodity treated with those canceled chemicals in another country that was attempted to be imported in this country would be illegal, would be adulterated, and FDA would not allow the import of that chemical, because there is no tolerance.

Senator MELCHER. That leads me into my last question. Would the responsibility of finding out whether an imported food product has the chemical rest with FDA?

Mr. SCHATZOW. That is correct.

Senator MELCHER. Thank you.

Senator LUGAR. Thank you very much, Senator Melcher.

We have been joined with the distinguished chairman of the Agriculture Committee, Senator Jesse Helms. Senator Helms, do you have an opening statement and/or questions?

The CHAIRMAN. I will have a statement for the record, and I do want to thank you. Senator Lugar and I swap committees every so often, and we are doing that this week. But he has a unique knowledge of this subject, and I appreciate his chairing this hearing today.

Senator LUGAR. Thank you very much.

We have had good attendance at our hearing this morning; eight Senators have participated, and we are grateful for that.

The CHAIRMAN. Good. That may be a record. [Laughter.]

Senator LUGAR. Yes; a high water mark. I think it does signify the interest in this very important subject.

We are indebted to both of you for coming and sharing with us very candidly your own points of view. Our invitation is open to continue that sharing, because it will be required if we are to be successful.

At this point, you are dismissed, and thank you again.

[Written questions from Senator Wilson to John Moore, EPA, and responses thereto:]

Question 1. During the second day of hearings on the reauthorization of FIFRA, the committee heard testimony in support of an amendment requiring national uniformity of tolerance levels on food use chemicals. Specifically, support was expressed by the United Fresh Fruit and Vegetable Association, National Food Processors Association and the Grocery Manufacturers of America (a copy of their statements is enclosed for your review).

Their support is premised upon problems which their members have encountered resulting from inconsistent federal/state standards for EDB and daminozide. While the committee is familiar with events surrounding EDB, it would appreciate receiving more specific data on the uses of daminozide, existing federal tolerances, and the proposals being considered by Massachusetts, Maine, and any other state that would result in a different standard.

Answer. Daminozide is a plant growth regulator registered under FIFRA to control the vegetable and reproductive growth of apples and other orchard crops, enhance shorter and more erect peanut vines, retard stem growth in tomatoes, and modify the stem length and shape of ornamental plants. Existing tolerances for daminozide are listed in the attached table. As you may know, on April 16, 1986, EPA issued a proposed rule (copy attached) to reduce the established tolerance for daminozide residues in or on the raw agricultural commodity apples from 30 parts per million (ppm) to 20 ppm, until July 31, 1987. EPA has already required a reduction in daminozide application rates for apples, effective January 1986, when the Agency formally approved revised product labels. Based on the reduced application rates, and existing residue data, EPA does not expect daminozide residues in or on apples to exceed 20 ppm. When EPA receives the results of new residue field trials, due for submission by the registrant in May 1987, we will reassess the 20 ppm tolerance and establish a new, permanent tolerance by July 31, 1987, if appropriate.

Massachusetts has adopted a three-year plan for lowering daminozide residue limits in apple sauce, apple juice, and infant and baby foods sold in the state as follows:

For heat-processed apple sauce and apple juice: a 5 ppm limit by October 1, 1986, a 1 ppm limit by October 1, 1987, and a "non-detectable" limit by October 1, 1988.

For infant and baby foods: a 1 ppm limit by October 1, 1986, and a non-detectable limit by October 1, 1988.

Massachusetts plans a public hearing in July 1987 to consider the technological feasibility of these non-detectable residue limits by 1988.

Maine has scheduled a public hearing for June 24, 1986, to consider the technical feasibility of the following daminozide residue limits that have been formally proposed for the state:

A non-detectable residue limit for baby food, effective October 1, 1986, for products in channels of trade.

A non-detectable residue limit for heat-processed food packaged October 1, 1986, or later.

No state other than Massachusetts and Maine, to our knowledge, has taken steps to adopt tolerances for daminozide that differ from national tolerance levels.

Question 2. Similarly, given that four different tolerance standards for EDB have existed for nearly two years, what has been the practical impact upon the businesses of your members. Does the situation impose additional costs upon your industries or their consumers and, if so, can you quantify them. Are there safety concerns which arise from differing state standards?

Answer. This question is apparently directed to the United Fresh Fruit and Vegetable Association, the National Food Processor Association, and/or the Grocery Manufacturers Association. EPA is unable to comment on the points raised by this question.

Question 3. Besides EDB and daminozide, is the Agency aware of any other food use chemicals which have more stringent state standards than existing federal tolerances. If so, would you please provide the committee with a list of these chemicals, their uses, and the different federal and state tolerance levels. To ask the question differently, if Congress were to enact a pesticide uniformity provision, what specific good use chemicals, in addition to EDB and daminozide, and which state's standards would be immediately affected?

Answer. EDB and daminozide represent the only cases where any state has adopted pesticide residue limits that are different from (more stringent than) national tolerances established under the FFDCA.

Question 4. The testimony from the Grocery Manufacturers of America states that the proposed uniformity amendment would affect "approximately 300 pesticides currently used on food crops, and the thousands of tolerances related to these uses." Except for EDB, daminozide, and any other pesticides which you may have identified in response to the previous question, is the committee to understand that the remaining federal tolerances—"thousands" of them—are uniformly being applied by each state.

Answer. Approximately 350 pesticides have registered food uses under FIFRA, and roughly 6,000 tolerances have been established under FFDCA for residues of these pesticide in or on particular raw agricultural commodities and processed foods. As indicated above, EDB and daminozide represent the only instances where there are state-established tolerances which differ from national tolerances under the FFDCA. In short, the answer to this question is yes, the vast majority of our pesticide tolerances are consistently enforced nationwide by FDA, USDA, and state agencies.

Question 5. Finally, section 1701 of S. 2346 would amend FIFRA to prohibit a state from establishing "any tolerance for a pesticide residue that is different from, or in addition to, a tolerance established under" federal law. Similarly, the testimony of the Grocery Manufacturers of America enumerates seven principles which should be incorporated in such a uniformity provision (see pp. 5–6). Would the Agency please comment upon and analyze these proposals and principles for the committee. Does the Agency support the concept of national uniformity and believe that it should be included in the reauthorization of FIFRA?

Answer. The testimony presented by the Grocery Manufacturers Association (GMA) urges the adoption of legislation to assure national uniformity in the regulation of levels of pesticide residues in or on food, as follows:

"First, legislation should establish the general rule that Federal requirements relating to levels of pesticide residues in or on food will constitute the national standard. Any State standard should be required to be identical, with the exceptions noted below.

"Second, any State should have concurrent jurisdiction to enforce the levels of pesticide residues that are established under Federal law.

"Third, any State official should be authorized to request Federal agency to change the Federal requirements, to reflect new information. The Federal agency should be required to give a prompt response.

"Fourth, any State should be permitted to request an exemption in order to impose a limitation lower than the Federal level, upon a showing of compelling and unique local conditions, or a lack of Federal interest, where the matter is primarily local in nature and local interests must be protected.

"Fifth, the Federal agencies should be required to establish an advisory committee comprised of State officials engaged in the regulation of the levels of pesticide residues in or on food, in order to receive sound advice on State issues.

"Sixth, petitions from State officials should be acted upon only by the highest Federal official responsible for the matter involved, and should not be delegated to lower officials.

"Seventh, whenever a State determines, on the basis of an adequate record, that a pesticide residue represents an imminent hazard to the citizens of its jurisdiction and that immediate action is necessary to prevent that imminent hazard, it should be free to do so as long as there is a prompt petition requesting Federal action."

EPA agrees that federally established pesticide tolerances should represent a national standard for consumer protection against unsafe pesticide residue levels in foods. As pointed out in the testimony of the GMA and the National Food Processors Association, there has been disagreement between EPA and certain individual states over appropriate tolerance levels for two pesticide chemicals: EDB and daminozide. However, such disagreements are rare occurrences involving highly controversial pesticides.

In addition to public health protection at the federal level, there is clearly a vital role for state health agencies to play in protecting their citizens. Where there are scientific uncertainties concerning a pesticide, such as daminozide, subject to federal tolerance requirements, a state may feel it necessary to step in and take action on its own. EPA is sympathetic to states' concerns and supports the states' role by sharing available health and safety data. On the other hand, independent state actions on tolerances levels do raise complicated issues concerning inter-state commerce. Such issues require consideration in context with larger issues of states' rights under the Constitution, and whether and when federal authority should preempt state and local regulatory authority. There is also the obvious issue of public confidence in a health-based regulatory system whenever EPA and a state disagree on appropriate tolerance levels based on the same data.

While EPA supports the basic concept of national uniformity, we are unable to take a stance on behalf of amending FIFRA in order to legislate uniformity according to section 1701 of S. 2346 or the proposal made by the GMA. First, since pesticide tolerances are established by EPA under FFDCA rather than FIFRA, we question whether, if such legislation is to be enacted, it would be appropriate to amend FIFRA to prohibit states from setting tolerances that differ from federal tolerances set under FFDCA. Second, we question whether the tolerance uniformity provision of S. 2346 would in fact resolve the issues of concern to the GMA and its sister associations. States would still have the option of issuing informal advisories on pesticide residue levels, if state agency officials felt compelled to do so. Public advisory statements issued by a state health agency could, as a practical matter, have nearly the same effect as state-imposed tolerances by raising citizen concern about commodities containing residues higher than state officials recommend. Third, we are concerned about the implications of this amendment in terms of states' rights under the Constitution.

While the first principle articulated by the GMA proposes a legislative change to ensure that federal tolerance requirements constitute the national standard for pesticide residue limits, the GMA's second through seventh principles suggest several exceptions to the proposed requirement that state standards for pesticide residues should be identical with federal tolerance requirements. Regarding the second of these principles, it should be understood that states presently do have concurrent jurisdiction with FDA and USDA to enforce pesticide tolerances established by EPA under FFDCA. Regarding the sixth of these principles, the committee is advised that all decisions on pesticide tolerances are made by the Director of EPA's Office of Pesticide Programs, and notices of proposed and final tolerance decisions are published in the Federal Register, with a formal comment period allowed for proposed tolerance actions. If FIFRA were amended to include a tolerance uniformity provision, the Agency would not object to any of the other exceptions suggested by the GMA.

DAMINOZIDE TOLERANCES

Commodity	Tolerance	Citation
Apples	30 ppm	40 CFR § 180.246.
Grapes	10 ppm	Do.
Tomatoes	40 ppm	Do.
Sweet cheeries	30 ppm	Do.
Peaches	30 ppm	Do.
Sour cherries	55 ppm	Do.
Peanuts	30 ppm	Do.
Peanut hay	20 ppm	Do.
Peanut hulls	10 ppm	Do.
Nectarines	30 ppm	Do.
Pears	20 ppm	Do.
Poultry, kidney	2 ppm	Do.
Eggs	0.2 ppm	Do.
Meat, fat, and meat byproducts of cattle, goats, hogs, horses, poultry (except poultry kidney), and sheep	0.2 ppm	Do.
Milk	0.02 ppm	Do.
Concentrated tomato products	320 ppm	21 CFR § 193.410.
Dried tomato pomace	600 ppm	21 CFR § 561.360.
Peanut meal	90 ppm	Do.

[Reprint From Federal Register / Vol. 51, No. 73 / Wednesday, April 16, 1986]

40 CFR PART 180 [OPP-300144; FRL 3082-3]

PESTICIDE TOLERANCE FOR DAMINOZIDE

Agency: Environmental Protection Ageny (EPA).

Action: Proposed rule.

Summary: This document proposes to reduce, on an interim basis, the existing tolerance for the herbicide daminozide (butanedioic acid mono (2,2-dimethylhydrazide)) in or on the raw agricultural commodity apples. This proposal to establish a reduced interim maximum permissible level for residues of daminozide in or on the commodity apples is a result of a special review that the Agency began in 1984. It is proposed that the reduced tolerance will remain in effect until July 31, 1987.

Date: Comments, identified by the document control number [OPP-300144], must be received on or before May 16, 1986.

Address: By mail, submit written comments to: Information Services Section, Program Management and Support Division (TS-757C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

Information submitted as a comment concerning this notice may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR Part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 236 at the address given above, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

For further information contact: By mail: Robert Taylor, Product Manager (PM) 25, Registration Division (TS-757C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

Office location and telephone number: Rm. 245, CM #2, 1921 Jefferson Davis Highway, Arlington, VA (703-557-1800).

Supplementary information: EPA initiated a special review of daminozide in 1984 based on the potential oncogenic risks of daminozide and UDMH (unsymmetrical dimethylhydrazine, a breakdown product of daminozide). Because of these potential risks to the public health associated with exposure to daminozide in food products, EPA proposed to cancel all food uses of the pesticide in August 1985.

As required by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA referred the proposal to the FIFRA Scientific Advisory Panel for peer review. After a public meeting in September, the panel concluded that the cancer studies were inadequate for predicting cancer risks from exposure to daminozide and UDMH in food products. The U.S. Department of Agriculture (USDA) was also asked to comment on the proposal. USDA argued that EPA has underestimated the benefits of continued use and urged EPA to reevaluate the need for cancellation.

After careful consideration of the recommendations of the Scientific Advisory Panel and the USDA, EPA determined that the data base was inadequate to support evaluation of the carcinogenicity of daminozide and UDMH and that dietary exposure was less than that estimated in the proposal to cancel all food uses. Based on this determination, EPA imposed interim regulatory measures that are a condition for the continued use of daminozide. These measures include the generation of data to provide EPA with the additional information needed to assess the risk, and actions to reduce dietary exposure to daminozide and UDMH, as discussed below.

To characterize the level of risk associated with dietary exposure to daminozide and UDMH, the Agency is requiring the following toxicology studies: oncogenicity studes in the rat and the mouse for both daminozide and UDMH, a full complement of mutagenicity studies on UDHM, and study in miniature pigs to determine conversion of daminozide to UDMH in mammalian species. Additional studies regarding the residues of daminozide and UDHM are also being required. These studies include a market basket survey, metabolism studies, analytical methodology, daminozide degradation to UDMH studies, livestock feeding studies, and residue field trials.

Measures to reduce dietary exposure to daminozide and UDMH include a reduction in application rates for apples and an interm reduction in the tolerance on apples.

The reduction in application rates, which was effective in January 1986 when EPA accepted the revised labeling, will decrease exposure to daminozide and UDMH from apples. With the reduced rates and using the current data, EPA has determined that the tolerance on apples can be reduced to 20 ppm. This document proposes to reduce the tolerance on apples from 30 ppm to 20 ppm, until July 31, 1987. When EPA receives the results of the residue field trials, due in May 1987, it will reassess the tolerance for apples and establish a new permanent tolerance by July 31, 1987, if appropriate. An adequate analytical method, spectrophotometry, is available for enforcement of a 20-parts-per-million (ppm) tolerance for daminozide.

Based on the data and information considered, the Agency concludes that the proposed tolerance would protect the public health. Further, the Agency has determined that, based on these data and information, the interim regulatory measures involving label changes will reduce the public's exposure to daminozide and UDMH until new and more acceptable data are available.

The Agency now proposes to amend the existing tolerance in 40 CFR 180.246 for the residues of daminozide in or on apples by reducing the tolerance from 30 ppm to 20 ppm, on an interim basis. This tolerance will expire on July 31, 1987.

Any person who has registered or submitted an application for registration of a pesticide, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, which contains daminozide, may request within 30 days after publication of this notice in the Federal Register that this proposed rule be referred to an Advisory Committee in accordance with section 408(e) of the Federal Food, Drug, and Cosmetic Act.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number [OPP-300144]. All written comments filed in response to this document will be available in the Information Services Section, at the address given above from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

EXECUTIVE ORDER 12291

Under Executive Order 12291, the Agency must determine whether a proposed regulatory action is "major" and therefore subject to the requirements of a Regulatory Impact Analysis. The Agency has determined that this proposed regulatory action is not a major regulatory action, i.e., it will not have an annual effect on the economy of at least $100 million, will not cause a major increase in prices, and will not have a significant adverse effect on competition or the ability of U.S. enterprises to compete with foreign enterprises.

This proposed rule has been reviewed by the Office of Management and Budget as required by E.O. 12291.

REGULATORY FLEXIBILITY ACT

This proposed rule has been reviewed under the Regulatory Flexibility Act of 1980 (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601 *et seq.*), and it has been determined that it will not have a significant economic impact on a substantial number of small businesses, small governments, or small organizations.

The measures to reduce dietary exposure to daminozide and UDMH are expected to be in place by the coming growing season. With the reduction in application rate, residues of daminozide in legally treated apples are not expected to exceed the level of the proposed reduced interim tolerance of 20 ppm.

Therefore, pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Agency has determined that this regulation will not have a significant economic impact on a substantial number of small entities.

Accordingly, it is certified that this regulatory action does not require a separate regulatory flexibility analysis under the Regulatory Flexibility Act.

LIST OF SUBJECTS IN 40 CFR PART 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests.

Dated: April 7, 1986.

DOUGLAS D. CAMPT,
Director, Registration Division, Office of Pesticide Programs.

PART 180—[AMENDED]

1. The authority citation for Part 180 continues to read as follows:

Authority: 21 U.S.C. 346a.

2. It is proposed that 40 CFR 180.246 be amended by removing "apples" from the tolerance listing for 30 ppm and inserting "apples" in the tolerance listing for 20 ppm, to read as follows:

§ 180.246 Daminozide; tolerances for residues.

* * * * * * *

30 parts per million in or on nectarines, peaches, peanuts, and sweet cherries.
20 parts per million in or on apples, brussels sprouts, peanut hay, and pears.

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[FR Doc. 86-8509 Filed 4-15-86; 8:45 am] Billing Code 6560-50-M.

The CHAIRMAN. The Chair will now call on Ms. Karen Darling, Deputy Assistant Secretary, Marketing and Inspection Service of the U.S. Department of Agriculture.

Ms. Darling, we are pleased to have you here this morning. Would you proceed with your testimony?

STATEMENT OF KAREN DARLING, DEPUTY ASSISTANT SECRETARY, MARKETING AND INSPECTION SERVICE, U.S. DEPARTMENT OF AGRICULTURE

Ms. DARLING. Thank you, Mr. Chairman.

It is a pleasure for the Department of Agriculture to be here this morning. I would first like to echo your opening remarks on the great spirit of cooperation that industry, the environmental groups, and even the Government have put together in trying to come to some consensus on FIFRA; and also to compliment our friends at EPA on their great efforts administratively to try to improve the administration of this very complicated law. As a regulator, I am glad it is not mine to regulate.

The agricultural community depends on the safe use of efficacious pesticides to help protect our agricultural production system and ensure our continued access to foreign markets. Unnecessary delays in the regulatory process under FIFRA can create costly uncertainty among producers and exporters who need to be able to make plans based on full knowledge of what products will be available to them.

While we recognize the need to ensure that regulatory decisionmaking is conducted in a timely and efficient manner, we believe that any proposed changes to the current law should not affect the ability of the Administrator of the EPA to base all actions on sound scientific data.

The EPA has a difficult mission, as we all know, and to achieve its goals, the Administrator needs to have flexibility in establishing deadlines and compiling data to support regulatory actions.

We certainly recognize that a thorough review of the effects a product may have on public health and the environment must continue to be balanced against the economic and social benefits regulated products can offer. We believe there is much merit in the proposals that are before the Congress, but we would like to offer some observations on issues that are of concern to the agricultural community.

We have a long history of cooperation with the EPA, and I must say it is better now than I ever recall it being before. As you all know, we are also involved with the EPA in biotechnology issues, and that has put us in very close contact.

One thing we have noticed in the S. 2215 bill is that it does not provide for notification of the Secretary of Agriculture when an interim administrative review is initiated. We believe that such a notification should be added, as it is crucial that we continue to be involved in any cancellation or classification review process. This bill would also delete the current requirement that the concurrence of the Secretary of Agriculture be sought for certain actions relating to minor-use pesticides. We believe that this requirement should be retained.

USDA has a well-established system for responding to scientific questions. This system allows us to provide EPA with vital data regarding pesticide products and uses so that a range of consequences of pesticide registration or loss of registration can be thoroughly considered.

S. 2215 would require the assessment of fees for reregistration of pesticides. While we would generally defer to the EPA on the question of fees, we are concerned that fees could become a disincentive to the development of minor-use products. If fees are implemented, we feel that an exemption should be granted for the IR-4 projects dealing with minor uses and for Federal agencies holding pesticide registrations.

Members of this committee know so well that U.S. agriculture is vital to our balance of trade. S. 2215 would amend that section of FIFRA that addresses the export of pesticides by requiring the revocation or amendment of tolerances and food additive regulations within 60 days of cancellation or other changes in the registration status of a pesticide.

We are concerned that this amendment could cause our trading partners to take action to restrict U.S. exports. A mechanism exists within the World Health Organization/FAO to resolve international issues regarding pesticide residues. In addition, the question of tolerance revocation for canceled pesticides has been addressed by EPA in a 1982 policy statement. Both USDA and the FDA have concurred with that statement. We do not believe that FIFRA is the appropriate vehicle to address the subject of these provisions.

EPA's authority to establish, amend, and repeal tolerances and food additive regulations comes from the Federal Food, Drug, and Cosmetic Act, not FIFRA.

Without the deletion of certain provisions and the addition of others, we cannot totally support either of the bills at this time. We do, however, believe that the deadlines in S. 2346 are more realistic, and that the bill provides the Administrator of EPA more flexibility to carry out his mission. S. 2346 also contains provisions that would maintain the availability of minor-use products and restore the requirement for consultation with USDA for minor-use products.

Mr. Chairman, we welcome this opportunity to work together with the Congress and with the EPA to ensure our common goal of protecting the environment. In its review of legislative action, we urge the committee to consider fully the impacts any proposed legislation will have on the agricultural community, small businesses, and importers and exporters, as well as, of course, the concerns of public health and the environment.

Only a flexible system based on the availability of sound scientific data and the thorough consideration of benefits and risks will allow us to properly protect and serve the American public.

This concludes my prepared statement. I have some experts with me in case you have questions that I cannot answer, and I would welcome any questions of the committee.

Senator LUGAR. Thank you very much, Ms. Darling.

In your opinion, would either piece of legislation result in higher pesticide costs to farmers? You indicated, obviously, that this impact must be measured carefully. Have you made any evaluation, taking a look at this legislation, as to whether a greater incidence of cost would occur?

Ms. DARLING. We have not analyzed thoroughly what the costs would be in either bill.

Senator LUGAR. Do you have an opinion on whether farmers should be exempted from liability if they have followed the pesticide label requirements carefully?

Ms. DARLING. Senator Lugar, we certainly feel that the farmer should not be held liable if he or she has followed the label requirements.

Senator LUGAR. Do you favor a uniform system of tolerances for pesticide residues?

Ms. DARLING. Well, I think that tolerances and action levels set by the FDA are helpful in establishing a uniform standard for use by the FDA and USDA in residue monitoring. Certainly, anything the EPA decides, is left to the USDA and the FDA to find that particular residue as set against that particular tolerance. I think without a tolerance system determining residues could be very arbitrary.

Senator LUGAR. Senator Helms, do you have questions?

The CHAIRMAN. I would like to have you elaborate a bit, possibly by giving me examples. On page 3, you say:

> S. 2215 would amend the section of FIFRA that addresses the export of pesticides by requiring the revocation or amendment of tolerances and food additive regulations within 60 days of cancellation or other changes in the registration status of a pesticide. We are concerned that this amendment could cause our trading partners to take action to restrict U.S. exports.

Give me an example. The Europeans?

Ms. DARLING. Well, yes; the Europeans are a good case in point. To use celery as an example, most of our trading partners demand that celery be treated with Trigard before importation. If we do not have use of that product, they are not going to import our celery. Unfortunately, the proposed cancellation of Trigard usually happens around harvest time.

Too often, chemicals, particularly pesticides, have worked as nontariff trade barriers, in both directions. For example, if we do not accept a French product treated with a particular chemical, then France is going to find our chemicals unacceptable. I think not having a worldwide inventory of all agricultural chemicals serves as a detriment to the entire community.

The CHAIRMAN. I cannot remember the name of the chemical, but we are using one that France does not like, for example, and they are using one that we do not like. So what do we do in a case like that?

Ms. DARLING. I think they are finding that in animal agriculture as well as plant agriculture, what each country does not like on the other side, and this situation certainly is hampering trade, but I am not sure what we do about it.

The CHAIRMAN. Are there numerous instances with just about all of our trading partners like that, or are the areas of agreement more numerous?

Ms. **Darling**. At this point, I think the areas of disagreement are more numerous.

The **Chairman**. Thank you.

Senator **Lugar**. Just following for a moment on Senator Helms' question, Is there no international communication on these problems? Is this subject to diplomacy with the Common Market, or through the State Department, or does the Agriculture Department have its own diplomatic emissary to try to clear up these problems?

Ms. **Darling**. Well, Senator Lugar, I personally feel that the Codex Alimentarius Commission, as set up by the WHO/FAO, is our best mechanism, partially because it is chaired by an employee of the Department of Agriculture and has been for the last couple of years. It is a forum in which each member country of the United Nations has an opportunity to speak to chemical residues, to speak to different areas of pesticides. And of course, it has frequent meetings.

Now, for that all to translate into action as to how those of us as policymakers and as legislators communicate on these problems will take a great deal of diplomacy.

Senator **Lugar**. Thank you very much.

Senator Melcher, do you have questions of the witness?

Senator **Melcher**. Secretary, are you familiar with the Burmeister report on incidence of cancer in Iowa farmers during the seventies? [7]

Ms. **Darling**. I am not, Senator Melcher, but I can see if one of my colleagues is. [Pause.] I am sorry.

Senator **Melcher**. Somebody will be familiar with it, eventually.

Ms. **Darling**. I am sure.

Senator **Melcher**. It seemed to indicate that farmers in Iowa were more likely to have cancer than a comparable group in Iowa urban areas. I just wondered whether the report had traced that to foreign chemicals or not. It might.

Ms. **Darling**. We will certainly try to locate that report and give you our opinion.

Senator **Melcher**. Thank you.

Ms. **Darling**. Thank you.

Senator **Lugar**. I would emphasize, please do try to find the Burmeister report.

Ms. **Darling**. Maybe Senator Melcher has a copy we could copy.

Senator **Melcher**. I do not.

Senator **Lugar**. Senator Melcher may be able to help you, however, in finding the source for the report.

Ms. **Darling**. Yes. We would be happy to work with you on that.

Senator **Melcher**. It was in one of the medical journals on cancer.

Ms. **Darling**. We will see what we can find out.

Senator **Lugar**. Thank you very much, Senator Melcher, and thank you, Ms. Darling.

Let me ask, if members of the next panel are all here, the Chair would like to proceed with them, and that would probably be helpful in terms of the use of your time as well as everyone else's.

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[7] The Burmeister report referred to above was subsequently received by the committee and has been retained in its files.

That would be: Dr. Jack Early, Ms. Nancy Drabble, and Al Meyerhoff.

Let me introduce the members of the panel formally. Dr. Jack Early is president of the National Agricultural Chemicals Association, and I understand he will be accompanied by Carl J. Kensil, chairman of the board of directors of NACA and vice president of CIBA-GEIGY Corp., and W. Scott Ferguson, general counsel of NACA in Washington, DC. Is that true, that you are accompanied by those two gentlemen?

Dr. **Early**. That is correct, Mr. Chairman.

Senator **Lugar**. And Ms. Nancy Drabble, director of Public Citizens' Congress Watch of Washington, DC, is with us, and Al Meyerhoff, senior attorney with the Natural Resources Defense Council in San Francisco, CA.

We welcome each of you. Would you proceed with your testimony, with the hope that you might summarize it within a relatively few minutes of time, and that would make it possible for us to then get into questions and answers with you.

Dr. Early.

STATEMENT OF DR. JACK D. EARLY, PRESIDENT, NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION, ACCOMPANIED BY CARL J. KENSIL, CHAIRMAN OF THE BOARD OF DIRECTORS, NACA, AND VICE PRESIDENT OF CIBA-GEIGY CORP., AND W. SCOTT FERGUSON, GENERAL COUNSEL, NACA

Dr. **Early**. Thank you, Mr Chairman. I appreciate you introducing my colleagues; that saves me having to do that. They are indeed with me. Mr. Ferguson is to my immediate left, and Mr. Kensil is second down.

Mr. Chairman, we represent the National Agricultural Chemicals Association, which is a nonprofit trade association representing some 92 companies that manufacture and formulate virtually all of the agrichemical products in the United States.

Mr. Chairman, it is a pleasure to testify before you today to support S. 2215, a package of amendments to the Federal Insecticide, Fungicide, and Rodenticide Act. I have an oral statement that I would like to submit for the record, and I will try to abbreviate it somewhat.

Senator **Lugar**. By unanimous consent, it will be included in the record in full.

Dr. **Early**. Thank you, Senator.

S. 2215 is a landmark piece of legislation. It is one of those rare bills that comes before the Congress with the combined support of traditionally adversarial organizations. NACA, with its 92 members, today joins with the campaign for pesticide reform [CPR] a national coalition of 41 environmental, consumer, and labor organizations, to urge enactment of S. 2215. A spectrum of such breadth speaks multitudes about the significance of this bill.

One of the most important beneficiaries of this legislation, we believe, is the farmer. Growers want to be assured that agrichemicals are safe for them and their employees and will not harm their land or the environment. The bill establishes definitive and orderly processes to bring all pesticide registrations up to date. If there is not adequate data to assure safety, new data will be required.

In sum, we believe the proposed amendments will give growers peace of mind and more confidence in the agricultural chemical technology.

Some user groups fear that S. 2215 will eliminate from the market some of the agrichemicals used on minor crops. We heard some comments about that earlier this morning, Mr. Chairman. Minor crops, as you have heard, are those crops representing several hundred very important and essential vegetable, plant, and other varied crops produced on limited acreages. They generally represent a very small market from a crop protection chemical standpoint, however. Registrants, to recoup their sizable investments, must seek out major crop/use registrations first. If there is sufficient return for the additional higher risks, they will generate the data for minor crop uses.

Some older products, in a few cases, will certainly disappear. But S. 2215 will have had nothing whatsoever to do with that fact. The cause, instead, is the massive 1985 EPA data call-in already underway to reregister all active ingredients for food or feed uses. Some products will be eliminated simply because the cost of generating the data for reregistration exceeds any potential return.

If S. 2215 were never invented or were rejected right now, this would still happen.

The prospective demise of some minor-use agrichemicals would be precisely as it is today. There have also been some concerns expressed about the cost of reregistration ultimately impacting the farmer. We have indicated in our legislation that we are willing to provide resources to EPA to speed up the process. Specifically, this means a onetime fee of $150,000 for each active ingredient reregistered. I wish to assure the committee and the agricultural community that the impact on prices will be minute and spread over the many crops and years—in fact, insignificant, based on the amount of money involved for the reregistration process.

We have not resolved every single issue in this legislation between NACA and CPR, but it is a solution aimed at the long term. It has incorporated a very significant percentage of longstanding differences between the two and a commitment to continue negotiating others.

NACA views S. 2215 as equitable. Frankly, Mr. Chairman, we would prefer some different language in some sections. It requires us to go a bit further in certain respects than some of our industry would like to. It is not perfect, but no compromise ever is.

Our objective now, as then, is to produce the best and safest products that we can for the farmer, so that he in turn can produce the best and safest products for the consumer. That is in everybody's best interest.

The key element in the production equation is innovation. In the agrichemicals industry, it is largely through innovation that we are able to develop and market new, safer, and more effective products for the farmer. Without such products, the American farmer, already in terrible shape, would be even worse off in his unending battle against nature's pests. Innovation requires considerable scientific know-how and high-risk capital investment. For every success, there are 15,000 to 20,000 failures. Innovation is so costly that it may require up to $40 million to bring a single new product from the laboratory to the farmer.

Our innovative capability is directly related to our ability and willingness of the industry to finance it. Yet it is being hampered by the Federal Government. We lose patent life to FIFRA's regulatory requirements.

We and the animal drug manufacturers are virtually the only industry shortchanged in this way. The patent law provides 17 years of protection. But we have been losing 5 to 7 years out of that 17. The patent law makes no provision whatever for other than even-handed treatment for all patent holders. The law does not say that all patent holders are to receive 17 years of protection except for those in the agricultural chemicals and animal drug industries.

Yet that is precisely the current state of affairs. A bill to provide redress is presently pending before the Senate Judiciary Committee. However, even that legislation, S. 1093, does not provide full restoration of patent term in every case. The impact of patent-term loss is very evident, Mr. Chairman. We see it in the very small number of new crop chemicals being registered every year.

I bring this up because the PTR issue has become intertwined with FIFRA. Part of our agreement with the CPR coalition includes removal of its opposition to moving PTR forward in tandem with the FIFRA package We are delighted to have the two in parallel and hopefully moving closer together. They represent the two legislative issues of the greatest importance to our industry.

If both this bill, S. 2215, and the Agricultural Patent Reform Act, S. 1093, are enacted in this Congress, the impact on us and therefore the farmer and the consumer will certainly be positive.

The committee can help immeasurably by moving forward with S. 2215 and, not incidentally, keeping S. 1093 in mind when it reaches the Senate floor which ideally would be roughly at the same time.

I will not attempt, Mr. Chairman, to go through the bill line by line, but instead, I would like to submit for the record an executive summary of the bill.[8]

In conclusion, Mr. Chairman, we will be delighted to answer any questions that you and the committee may have.

Senator LUGAR. Thank you very much, Dr. Early.

Dr. EARLY. Mr. Chairman, my colleague, Mr. Kensil, has a brief statement—I should have alerted you in the beginning—and if he could make that now.

Senator LUGAR. All right. If it is a brief statement, that will be fine.

Dr. EARLY. Thank you.

Mr. KENSIL. I will do my best to summarize.

Mr. Chairman, I am Carl Kensil. For a living, I work for the agricultural division of CIBA-GEIGY Corp., in Greensboro, NC, and I am currently chairman of NACA's board of directors.

We appreciate this opportunity to testify before the Senate Agriculture Committee today in full support of the package of amendments contained in S. 2215. The language was worked out with the campaign for pesticide reform during hundreds of hours of negotiations over a period of more than 1 year.

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[8] See p. 143 for additional material inserted by Dr. Early.

And, as Jack Early has already noted in his testimony, for us to join with our traditional adversaries to amend the Nation's basic agrichemicals law is indeed unique.

We sincerely hope this is a permanent change. All interests would be better served, particularly the public and the farmer, to whom we have an obligation, and I hope our traditional adversaries will give more credit to agrichemicals for their vital role in helping feed our Nation and others.

For a long time now, we have heard the concerns of our critics in the various environmental, consumer, and labor organizations. In all candor, some have had merit. Some have not. We have heard the accusations about our past unwillingness to make more health and safety data openly available. What we have not always heard from our critics is just how such a thing could be done without subjecting proprietary data valued in the multimillions of dollars to serious, competitive harm. But we have continued to look for a way to share these data.

We have heard and been sensitive to repeated criticism about the integrity of data supporting a few old commodity chemicals whose entry into the marketplace predated modern detection technology by several decades. And we have debated among ourselves about how we might respond to publicly expressed concerns about export notification, EPA's missed reregistration deadlines, public access to health and safety data prior to registration, EPA's cancellation procedures—and all the other issues that have made their way into the headlines.

We know full well that we are more than simply manufacturers and formulators of products that enable our farmer customers to control ever-present insects, weeds, and diseases. We understand that in one way or another, every American is exposed to the products of our industry. That recognition puts an even bigger burden on us.

What we are here to tell you, Mr. Chairman, is that we accept our responsibilities to our customers and the public at large. Their concerns are really identical.

And it is in that spirit that we support the NACA/CPR legislative package designed to resolve many of the specific concerns I have listed.

The decision of our industry to support this legislation did not come easily. We have had some cliffhanger debates over various parts of this bill.

As I am sure you will hear shortly from the CPR representatives, this legislation does not satisfy every concern of the public interest groups. Nor, as I have already indicated, does it put a smile on every member of our board of directors—but they all voted for it.

We support this legislation as evidence of our industry's willingness to provide added guarantees in law that our products are just as safe or safer than we have always said they are.

Thank you.

Senator Lugar. Thank you very much, sir.

Let me ask Ms. Drabble and her colleague, Mr. Meyerhoff, do you wish to testify separately, in tandem, or how would you like to proceed?

Ms. **Drabble**. We are each going to use our 5 minutes, Mr. Chairman.

Senator **Lugar**. Very well. Please proceed.

Ms. **Drabble**. Before I start my testimony, I would like to mention that I am familiar with the Burmeister report. In fact, I have got a copy of it back at my office, and I would be glad to submit it to the committee.[9]

Senator **Lugar**. That would be helpful, I think.

Senator **Melcher**. I think we had better make it a part of the record.

Senator **Lugar**. Very well.

STATEMENT OF NANCY DRABBLE, DIRECTOR, PUBLIC CITIZEN'S CONGRESS WATCH

Ms. **Drabble**. It does show that farmers in Iowa do suffer higher cancer rates, and it suggests that pesticides might be implicated. In addition, there have been epidemiological studies in several other Midwestern States, including Nebraska and Wisconsin, which also show higher rates of certain kinds of cancer, and suggest a correlation with the use of pesticides.

S. 2215 is a very carefully negotiated compromise which reflects more than 1 year of negotiations, and as the representatives from NACA mentioned, it has the full support of our coalition of more than 40 environmental, and consumer and labor groups, and also the full membership of NACA. It is rare for such traditionally contentious groups to agree on anything, let alone a major piece of environmental legislation, and we hope that the introduction of this bill by you and Senators Proxmire and Leahy is the first step in bringing some order to the regulation of chemicals.

This agreement has already received widespread editorial support from regions across the country and has received coverage in more than 25 States. We have included some of those press clips in our testimony for you to take a look at.

While it is not a panacea and involves hard choices for all the negotiators, we believe this legislation will result in major improvement in a statute that we believe does not now protect human health or the environment.

Before Mr. Meyerhoff addresses some of the substantive changes that the bill would make in the law, I would like to briefly review the negotiating process.

As the committee is very well aware, for many years, a stalemate has existed between industry and environmental and consumer groups on needed amendments to FIFRA. Starting last February, we began discussions with the industry about possible amendments to FIFRA. After dozens of often difficult and time-consuming meetings, we reached an agreement in principle last September, which eventually resulted in S. 2215 6 months later.

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[9] The Burmeister report has been retained in the committee files.

Recognizing that issues relating to FIFRA are of vital interest to a variety of constituencies, we have also met periodically and discussed these and other amendments to FIFRA with a variety of other groups, including the Farm Bureau, the National Pest Control Association, the National Forest Products Association, the National Agricultural Aviation Association, the United Fresh Fruit & Vegetable Association, and a number of other trade associations. We sought their views and where possible tried to work out differences.

At this point, we have definitely set the world record for meetings, and I am sure that as this process goes forward, we will break that record.

In addition, NACA circulated various early drafts of the proposed legislation to 20 trade associations and also had a variety of meetings, and we also made a variety of drafts public and circulated them to different groups.

In addition to that, since last March, the campaign for pesticide reform has been holding discussions with the Farm Bureau on certain amendments we would like to see, such as improved training for pesticide applicators, clarifying EPA's rseponsibility for the protection of agricultural workers, and promoting the maintenance of adequate records when pesticides are applied. While some progress has been made on certain of those issues, those negotiations have not been completed yet.

Finally, throughout this process we have met frequently with Assistant Administrator Jack Moore and have sought EPA's views and tried to take their concerns into account. And also I might mention that since the House hearings were held last month, we and NACA and some other parties have been engaged in further negotiations over on the House side to try to answer some of the concerns that EPA raised this morning, and we are hopeful that some of those concerns can be worked out before the bill is marked up in the House or in the Senate.

Obviously, despite all these hundreds of hours of discussions and attempts to reach consensus, obstacles still remain. There are those who may oppose the legislation or who perhaps would even like to weaken the law. As the legislative process begins, some who did not want to negotiate in the first place will advocate weakening amendments. And while necessary adjustments can and will be made in the legislation—and that is what the legislative process is all about—we hope that the committee will resist attempts to undermine the compromise, since this legislation is a delicate balance which involves hard choices for everybody. We hope that that delicate balance will not be upset by major amendments of that sort.

Finding agreement on a series of FIFRA amendments supported both by NACA and by our coalition of environmental, consumer, and labor groups, is an achievement and presents an unprecedented opportunity for Congress to act. We hope that Congress will take advantage of that opportunity.[10]

Thank you.

Senator **Lugar**. Thank you very much, Ms. Drabble.

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[10] See p. 150 for a reprint of the joint prepared statement of Ms. Drabble and Mr. Meyerhoff.

Mr. Meyerhoff.

STATEMENT OF ALBERT H. MEYERHOFF, SENIOR ATTORNEY, NATURAL RESOURCES DEFENSE COUNCIL, SAN FRANCISCO, CA

Mr. MEYERHOFF. Thank you, Senator. I will be very brief.

This legislation is quite complex and deals with a host of issues. Time will not permit going into all of those issues this morning.

Quite briefly, it deals with such issues as requiring full health and safety testing of pesticides by a date certain; imposing a reregistration fee to generate sufficient resources to the Agency to complete an independent review of that data; authorizing the Agency to cancel chemicals where data is found to be marginal or invalid since the Agency now is of the view that they lack that legal authority. It will create a new system of regulating pesticide inert ingredients; it will streamline cancellation and RPAR procedures; it will provide notice to foreign countries of risks posed by chemicals that are exported; it will prohibit the importation of food into the United States containing residues of chemicals which are either banned or not registered here. It will create a community right to know for citizens who reside near chemical plants about the products that are being produced at those plants.

And includes a host of other measures.

I would like to focus my remarks, however, on the two issues that were stressed by EPA in their testimony, reregistration and RPAR and cancellation procedures.

We are in active discussions or negotiations with EPA on those two issues. In 1972, Congress mandated that pesticides in the United States be reregistered. Fourteen years later, in a new report NRDC has just completed on reregistration, we found that only 16 active ingredients are actually reregistered over those 14 years.

The National Academy of Sciences in 1984 similarly found that only 10 percent of pesticide active ingredients that are marketed in the United States have adequate data to allow a full health and hazard assessment.

And a 1982 House Agriculture subcommittee report previously found that 85 percent of the pesticide active ingredients sold in this country lack sufficient data to determine their carcinogenicity; two-thirds lack adequate data to determine if they cause birth defects; over 90 percent lack adequate data to determine if they cause genetic mutations.

In short, we have been regulating out of ignorance.

These chemicals, however, are in our drinking water, they are in our food supply, they are in the workplace.

I think all parties agree that that reality has to change, and change as rapidly as possible. We went through a very long negotiation process with NACA on reregistration. We came up with a framework whereby reregistration would be completed in 7 years time. The EPA over 2 years would identify the "gaps" in the data that needed new tests; the industry would then generate new studies within 4 years—a chronic toxicology study takes 2 years time at most. And the Agency would then "reregister" the chemical—that is, determine its safety—in 1 year's time.

This legislation was modeled on the California Birth Defect Prevention Act, S.B. 950, Petris, which was passed with broad bipartisan support in the California Legislature and signed by Governor Deukmejian 2 years ago. We think it is a workable system.

Like reregistration, EPA's record on cancellations and special reviews is equally dismal. I think most of you are familiar with the EDB experience. In the early seventies, the National Cancer Institute determined that EDB was a potent animal carcinogen and probable human carcinogen. It went into RPAR, an intensive and expedited regulatory review, in 1977, it was finally canceled in 1984, 7 years later. EDB is not a unique example. It is the norm. Pentachlorophenol, a widely used wood preservative, was linked to birth defects in the early seventies. It contains a dioxin contaminant linked to cancer. It finally went into RPAR in 1977. We are now in 1986, and it is still on the market. EPA finally completed the Penta RPAR 1½ years ago, but administrative hearings are now going on, and the public continues to buy Penta over the counter; it is also used on children's playgrounds—and in millions of homes.

And there are a whole variety of other examples.

We have agreed in this compromise to something much less than what was in the original "Harpers Ferry" legislation we were supporting in terms of deadlines for these special reviews. Under S. 2215, special reviews would be completed within 1 year, unless circumstances require the generation of additional data, in which case an extension of another year would be allowed. A 2-year maximum period for completion of special review would be put into place.

I would like to correct what I believe was a mistake by Mr. Moore this morning. S. 2215 does not require RPAR's to be initiated on a risk-only basis. To the contrary, it specifically provides that the Agency consider exposure in making that decision. What it would preclude the Agency from doing is delaying the initiation of an RPAR in order to generate additional exposure data for inexorable amounts of time. I think that is a very important distinction, because over and over, we have had cases where chemicals were thought to present serious public health hazards where cancer or other data demonstrated a risk to the public, but they were simply left in limbo for many, many years. That system, I think, undermines the trust of the American people in the industry, in government, in all of us.

We believe that this bill will change that.

We believe the bill is an important step forward, and are hopeful that we can secure its passage this year.

Thank you.

Senator LUGAR. Thank you very much, Mr. Meyerhoff.

Let me commence the questioning by asking a question for Senator Leahy, who left this with me as he departed the hearing.

He says, "I understand that one of the issues that has been a matter of concern, ground water contamination, has now been resolved. Can you tell the committee about the compromise that has been reached?"

Anybody can respond to that.

Dr. EARLY. Let me comment first. The reason I think we are hesitating a little bit here is that just recently, our negotiators have reached a tentative agreement in that area of ground water. I hope the chairman of the committee will understand that it is at a very sensitive stage now. It is an agreement that has not been shared with the members of my organization, nor with the members of the environmental organization, and I think it would probably serve no real useful purpose to put that into the open at this time.

It is our hope, our sincere hope, that we can finalize this agreement that has been brought forward to our respective organizations by our negotiators, and that we can agree on that proposal, and then at that time, ask you to look at that proposal.

Senator **Lugar**. Very well.

Let me ask any of you about the general suggestion of Mr. Moore of EPA this morning that the registrants might be more responsible for determining data needs for reregistration. In short, as you heard his testimony, he was describing how the entire system might be changed to provide for more expeditious decisionmaking. Likewise, there may be less incidence of cost in the total system, while more of the cost will be borne by the registrants.

As any of you in this coalition this morning have reviewed that situation, do you have a comment?

Dr. **Early**. I may comment first, Mr. Chairman—Nancy and Al may comment later—but it is my industry that must come up with the information. We are aware, based on our discussions with EPA of the resource requirements for the reregistration process. EPA has advocated that we take over a large burden of this reregistration process.

I do not believe and we do not believe that it is necessarily in the public interest or our interest that we should assume that large responsibility.

What we have indicated we are willing to do is that we are willing to go back and ask our companies to evaluate at least some of the critical studies that are part of this registration process. We refer to that as the CORT studies, which are the chronic studies, the oncogenicity studies, the reproduction and the teratology studies. These are usually the basic health studies involved in pesticide registration or reregistration.

I cannot speak for all my companies right now, because they are really evaluating that. But there may be some way we could do that as registrants to assist in that process, to relieve that labor requirement that is in EPA's hands right now.

Senator **Lugar**. Thank you.

Ms. Drabble.

Ms. **Drabble**. We also participated in discussions with EPA, and our feeling is that there may be a possibility for the registrants to identify some of the data gaps, but the critical point from our viewpoint is that EPA then must examine what the registrants have done and find out whether the registrant has correctly identified those data gaps. It is the job of the regulatory agency to make an independent judgment about what the registrants have said, whether they have identified the correct studies that need to be replaced, because in some instances, there may be some studies that the registrants just do not think need to be replaced but EPA disagrees with that judgment and thinks that they do need to be replaced.

So as long as EPA is required to give some independent review of the registrants' work, we think that that process maybe can work.

Senator LUGAR. Let me ask, is it possible that all the parties at the table take a look at this EPA suggestion, as the same invitation that I suggested to Mr. Moore that he might think of some draft language, that you might likewise think of that.

It occurred to me that his suggestion, even if you do not buy it in its entirety, was an important one, because clearly, if there are 40,000 studies to be considered by EPA to get through the remaining 420 reregistrations, regardless of the deadlines that are posed in any draft bill we have, we know that some frustration is going to occur. The public will wonder why we are legislating in a way that clearly was deemed impossible by all of the parties that were involved at the outset. To avoid that type of the public distrust and, really, to expedite things that are of value to all parties, it seems to me there might be usefulness in everybody consulting on the basis of what has occurred this morning.

Mr. MEYERHOFF. I think everybody agrees with that. Indeed, I think that what the environmental interests certainly did not want to do was offer a false promise to the public, and that is why the legislation that you introduced Senator Lugar includes a reregistration fee that would generate additional resources to the Agency to make this work, and not simply put dates in the law that have no meaning.

Senator LUGAR. Yes of course; the companies have decided it is also in good interest, even at considerable expense to them. I think the question now is, so that the money is well-spent, whether it is private or public, as we try to think through the expedition of the procedure.

Yes, Dr. Early.

Dr. EARLY. If I may comment, Mr. Chairman, the committee should understand and recognize, I think, what has been tremendous progress on the part of our group and EPA. Early on, EPA was looking at a process that was going to take something like 20 years for reregistration. We have proposed a procedure that would take 7 years.

We are still in constant negotiations, and I think you heard Dr. Moore say we all want to get to the same goal; we are just looking for the right road to get there. And we are still in that process. So I do not think there is any question that we can reduce that timeframe significantly; hopefully, we can cut it in half, at least in half. I think we should recognize that that is significant process in itself.

Senator LUGAR. It sure is.

Senator Helms.

The CHAIRMAN. Your negotiations on the ground water, when do you think you will come to a meeting of the minds?

Dr. EARLY. I think in order to make it a part of the process that is ongoing right now here and in the House, that we are going to have to reach some kind of agreement on that within the next few weeks. Now, we are talking weeks and not months, and I hope that my colleague would agree.

Mr. **Meyerhoff**. Yes, we have circulated the agreement that the negotiating team has reached to our principals and hope to have a response within that time.

The **Chairman**. You have circulated it to whom, sir?

Mr. **Meyerhoff**. To the more than 40 groups that are part of our coalition.

The **Chairman**. Thank you.

Senator **Lugar**. Senator Melcher.

Senator **Melcher**. Dr. Early, you mentioned 5 to 7 years out of the 17. I do not understand that. Could you clarify that?

Dr. **Early**. Let me see if I can very briefly clarify. What happens in the normal process of the invention and development of an agricultural chemical is you invent the particular chemical use, and you apply for a patent. You may very well get the patent issued within 1 year or 2 years or something of that order. Then, in order to sell the product to the farmer, you must go through the very extensive evaluations of health and safety studies, and you also must go through an extensive review by EPA.

So during that process, you cannot move into the marketplace even though you get your patent, but you may lose years to the testing time and the EPA review time. The issue is, as we have said before Senator Mathias' subcommittee, simply one of equity. We should be entitled to practice our invention for 17 years. This legislation has been by and large supported by this industry, and it has passed out of the Senate subcommittee and is now before the Judiciary Committee itself.

Senator **Melcher**. In other words, after you have got the patent and you have gone through the registration process, you do not want to count the time used during the registration process?

Dr. **Early**. That is right. And you are not going to get all of that back, but you are going to get the fair amount of that back that you lose through the registration process.

Senator **Melcher**. It is my understanding from testimony from the Department of Agriculture that S. 2215 does not have Department of Agriculture participation in the interim—they are not even notified on the interim administrative review by EPA. Is that correct?

Ms. **Drabble**. I think there is a misunderstanding on that point, because S. 2215 does not change current law. Under current law, EPA must ask USDA for their comments on proposed cancellations of pesticides within a certain number of days before they come out with their decision. That would remain.

So, when EPA goes through a special review they still would send their proposed decision over to USDA, after USDA——

Senator **Melcher**. The point was they were not notified when an interim administrative review starts.

Mr. **Meyerhoff**. Those reviews are published in the Federal Register. They would receive full notice, as the rest of the public does, and as the current system operates, they regularly participate in special reviews now.

Senator **Melcher**. They do not have any objection to having EPA notify the Department of Agriculture when they start to commence an interim administrative review?

Dr. **Early**. We have no problem with that.

Mr. **Meyerhoff**. If that would help gain their full support for the rest of the legislation.

Senator **Melcher**. On minor uses, you do not want that law changed, do you? The Department testified that there is some change in the law in S. 2215 on minor use as it relates to the Department of Agriculture.

Ms. **Drabble**. In the conditional registration section, which tightens up the granting of conditional registration, there is a special exemption for minor uses. The way it works is this. If there were data missing on cancer effects or other important chronic health studies, such as neurotoxicity, then EPA would not be able to grant a conditional registration. But that provision does not apply to conditional registrations for minor uses.

So even if you were missing some of those studies, and you wanted to get a conditional registration for a minor use, you still could.

However, if a chemical is in special review—and there are very few chemicals that are in special review—but if it has been put into special review because of possible risk of human dietary exposure, then in that case, a chemical could not get an additional use under a conditional registration. The reason for that is that only chemicals that have been identified as potential hazards are the ones that are most suspect, are the ones in special review, and that is not the time to start adding additional uses until that question has been resolved.

Senator **Melcher**. My question did not go so much to the process changes, except if the Department of Agriculture were left out in the case of minor uses. Is that just a different interpretation that they placed on it?

Ms. **Drabble**. I really cannot think of any way in which the legislation would leave the Department of Agriculture out on minor uses. I do not know of any way S. 2215 changes the current law on that.

Senator **Melcher**. However, what if the Department finds some difficulty with their participation on minor uses as it exists now? Here is their statement.

"S. 2346 also contains provisions that would maintain the availability of minor-use products and restore the requirement for consultation with USDA for minor-use products." I am referring to that last clause of "restore the requirement for consultation with USDA for minor-use products."

Does that create any problem with you?

Mr. **Meyerhoff**. I do not know what it is referring to.

Mr. **Ferguson**. I believe the reference is to the conditional registration. There is a deletion in our bill, S. 2215, that was not made in the other bill you referenced. The deletion of the Department of Agriculture was incidental to another deletion, really, the objective, and that is the current law of allowing the grant of a minor-use conditional registration when the product is in special review. Under those circumstances, the Department of Agriculture is consulted.

What is done in S. 2215 is that exception for conditional registrations is deleted; and it is only incidental that the Department of Agriculture is mentioned.

Mr. **Meyerhoff**. That is right.

Senator **Melcher**. Thank you very much.

Senator **Lugar**. Let me ask how does the issue of patent term restoration relate to your compromise?

Dr. **Early**. Well, they have put the microphone in front of me, Mr. Chairman, so I guess I will try to answer it.

Let me back up almost 3 years ago. There was some legislation that came through this body over here, and the House, and ultimately signed into law that gave an adjustment to the pharmaceutical industry a couple years ago. And they were essentially in the same position we are—loss of time through registration and new drug application process. So we supported a separate bill, essentially, the one that just passed out of Senator Mathias' subcommittee, and before the House Judiciary Committee a couple of years ago. We were, I thought, if I could use the term, moving along reasonably well; people understood the inequity of the situation, and we felt we were making a lot of progress. Some of our colleagues from the environmental community suggested to some of their colleagues on the Judiciary Committee that it would be helpful if our industry would be willing to deal with FIFRA at the same time we looked at patent-term restoration.

Obviously, we ran into a little bit of a block at that time and were not successful in getting it reported out of the Judiciary Committee and recognized the advantages of sitting down and trying to deal with issues on both sides. The environmental and public interest groups had some issues we wanted to discuss, and so that is how the process started.

We did agree that we would try to work collectively to move both of these pieces of legislation along at essentially the same rate, to the extent we could, of course. Obviously, we do not control the legislative process. We agreed to work together on both of those pieces of legislation.

Senator **Lugar**. Can the proposed registration fee that has been suggested in S. 2215 and part of your compromise, be modified or amended in any way that you could suggest to protect the interests of smaller producers and/or minor-use pesticides?

Obviously, that is a bone of contention, and has led to alternative legislation. Can you make any contribution at this point in the hearing that would be helpful?

Dr. **Early**. Well, I can certainly start the comments on this, and Mr. Kensil, as a manufacturer, may be able to add something from a personal standpoint on this.

I think, as we said in our testimony here, that I do not believe and our industry does not believe that $150,000 is a significant factor when you are looking at having to fill data gaps on these CORT studies that I talked about. The cost of these studies is in the neighborhood of $3 to $5 million. So it cannot be a very large factor in that process.

Also you must recognize that we are talking about $150,000 for an active ingredient, not on a formulation. Those that formulate that product are exempted from paying that fee. So if you buy an active ingredient and you formulate, you do not pay that fee. The manufacturer who registers that active ingredient is the one who pays it. And in most cases, as you heard early on from Mr. Moore, that most minor crops are products that are initially registered on what we call major crops—corn, soybeans, and cotton.

So the cost is going to be spread over a number of crops out there; major and minor crops.

In the final analysis and I think we need to put the pencil to it, you are going to end up with almost insignificant costs to minor crops or to anyone who uses that product.

The real decision to register a product or reregister a product is whether you are willing to step up to the issue of spending millions of dollars, not $150,000.

Senator **Lugar**. Let me just add one thought. We will hear testimony this afternoon from American Farm Bureau Federation, and I quote; they say,

> We are concerned about the establishment of reregistration fees. These fees, totaling $100,000 per active ingredient, are apparently intended for use by the Agency to hire additional staff to comply with the expedited reregistration process. These fees, which will total $70 million, will undoubtedly be passed along, driving up production costs to farmers and ranchers and further erode net farm income.

What can any of you say to American farmers with regard to these allegations, which I am certain are an important part of our discussion?

Dr. **Early**. Well, I hope I tried to answer that a minute ago. You know, we do not see it as being a large factor out there to the American farmer. It does not make any sense to us to put that increased cost on the back of the farmer right now, when he is having a tough time.

I think you could come up with that large of a number, if you put a pencil to the arithmetic. I am not sure the amount of money is going to be quite that large, frankly.

You are going to see some of these products that are going to fall by the wayside because of the health and safety studies, not because of the $150,000.

I just do not believe it is going to be that additional cost to the farmer.

Mr. **Kensil**. If I may, Mr. Chairman, as a supplier of active ingredients, if one can theorize that that $150,000 cost is going to be borne by the manufacturer or by the taxpayer, if the work is to be done, then the revenue is going to have to come from somewhere.

So I would consider the $150,000 fee only one element of dozens of things that have to be considered in establishing the pricing of my products. I think it is relatively insignificant.

Ms. **Drabble**. I think another reason why it is insignificant, to reiterate what Dr. Early has said, if you have an active ingredient that has 15 uses, and that perhaps is in 100 formulations, there still is only going to be one $150,000 fee for that active ingredient. So that amount is going to be spread out across a very large universe.

In addition, if there is more than one registrant, the fee will be divided among the several registrants; formulators are totally exempted from the reregistration fee.

So for those reasons, we do not expect that you would actually see any effect on the pricing of products; and in particular because EPA has already called in the data for the food crops for the CORT studies, so last year registrants already had to make a decision about whether they were going to replace the missing studies.

If there was going to be a bad effect on minor-use crops, we would have seen it already. EPA, as they testified this morning, has said that has not happened. The minor uses have not dropped out; they have not seen bad effects. So experience has already shown us that there is not going to be a problem with minor uses from reregistration requirements.

Senator LUGAR. I asked Mr. Moore of EPA earlier for his estimate of how many of the 420 ingredients might drop by the wayside prior to going to the registration process, and presumably the $150,000 fee.

Do any of you have estimates as to how much of a burden we still have? Is it 420, or substantially less?

Dr. EARLY. Mr. Chairman, I do not think any of us here at the table can give you a good number on that. It depends on how the companies are going to react.

I should also call to your attention as we talk about this $150,000 fee issue that there is a provision if I recall in the bill that would reduce the fee for nonagricultural active ingredients.

Mr. MEYERHOFF. Correct. It is up to 50 percent.

Dr. EARLY. So the burden is one-half on nonagricultural pesticides than what it is on agricultural pesticides.

Mr. MEYERHOFF. It is also spread over 7 years. We are not talking about a lump sum fee in 1 year.

Senator LUGAR. Should farmers be exempt from liability if they have followed label requirements?

Mr. MEYERHOFF. We would be quite willing to speak to that issue. No; we do not believe that they should be.

There are a variety of reasons for that. First, we think that those issues probably should not be dealt with in FIFRA in the first instance. Moreover, we have a cost benefit statute here where liability is built into the scheme. This is not a health-based standard. If one purchases a product with the knowledge that risks are involved—that it could get into ground water or it could cause cancer or birth defects or whatever—and then it gets into ground water, I think that liability should be apportioned. Now, that does not mean that there are not mechanisms in the current tort system to deal with that. We think that those issues are best addressed in that system and in the individual States.

Ms. DRABBLE. Under the current tort system, if the farmer has followed the label and can show that he has, and he has been sued, that point will be made to the jury, and they do take that into account in the State law. We are not aware of instances where farmers have been held liable under those circumstances, because if they followed the label, the judge or the jury would decide that they are not liable—under the current law.

Senator LUGAR. Should local jurisdictions have authority to regulate pesticides?

Ms. DRABBLE. We think that they should. If a State wants to take away the power of the local jurisdiction to regulate pesticides, it can. In fact, that happened in California. In California, one county wanted to regulate a pesticide, and the State legislature decided to take away that power. In fact, that has happened in a number of other States. So we think the issue should be between the State and the local jurisdiction, and the State can decide whether or not it wants local jurisdictions to regulate.

There are some arguments in favor of local jurisdictions having that power. One example I like to use is if Ocean City decides it does not want pesticides sprayed on its beaches on the weekends, that is a matter best left to Ocean City. They know best about what their needs are in that area. Similarly, some local jurisdictions have decided that they want to have posting before lawns are sprayed so that neighbors can take precautions and keep their children from playing on the lawn when there is going to be spraying going on; or posting before the city sprays so people can take precautions. That is the kind of ordinance that some local jurisdictions have passed, which we think is quite reasonable.

Senator Lugar. Senator Melcher.

Senator Melcher. Mr. Meyerhoff, on this question of liability, did I understand you correctly that if the farmer follows a labeling, he could still be liable?

Mr. Meyerhoff. I think theoretically; I would not say it is impossible. But most tort cases, as Ms. Drabble indicated, have allowed that issue to go to the jury and have allowed evidence to be shown to the jury that the farmer was simply doing what the label provided. We are unaware of any case where, in those circumstances, a farmer has actually been held liable. Of course, if in that hypothetical case, a farmer were held liable, he would nonetheless still have recourse against the codefendant chemical company.

Senator Melcher. Well, why isn't this the proper arena? If I understood you correctly, you said this FIFRA bill is not the proper place to address this liability of the farmer. Why isn't it? What is the label for?

Mr. Meyerhoff. The label is to instruct on the proper use of the chemical. FIFRA is to regulate——

Senator Melcher. Safe use?

Mr. Meyerhoff. Safe use.

Senator Melcher. Healthful use?

Mr. Meyerhoff. Right. But not to tamper, I believe, with the tort system. If the tort system is going to be reformed, there are appropriate committees in the Congress where those efforts should be made. But it strikes me in the first instance that the tort system in this area should not be reformed.

Senator Melcher. This is a Federal law?

Mr. Meyerhoff. That is correct.

Senator Melcher. Would you say the Federal tort system would apply to everybody equally?

Mr. Meyerhoff. No.

Senator Melcher. That is under State law, is it not?

Mr. Meyerhoff. That is right.

Senator Melcher. The labeling is Federal?

Mr. Meyerhoff. Yes.

Senator Melcher. So, it follows the requirement of Federal law.

Mr. Meyerhoff. And the issue of whether the following of that requirement exculpates from liability, it strikes me, should be left to the individual States.

Senator **Melcher**. That is interesting. I think it is a pretty far-reaching law when we want it to be farreaching.

Mr. **Meyerhoff**. We certainly want it to be more far-reaching.

Senator **Melcher**. Regarding the ground water; what farmer knows when it gets into ground water? Is he supposed to know?

Mr. **Meyerhoff**. I think you have a circumstance where for many years it was presumed or believed that such chemicals would not get in the ground water, and farmers then——

Senator **Melcher**. Farmers do not know what gets into ground water. I do not know what gets into ground water.

Mr. **Meyerhoff**. In California, farmers have become very well aware of what gets into ground water, in my State.

Senator **Melcher**. Because something was dangerous?

Mr. **Meyerhoff**. Because we have some 2,000 wells that contain 57 different pesticides.

Senator **Melcher**. Yes; and it has become a public health hazard.

Mr. **Meyerhoff**. It has indeed.

Senator **Melcher**. So then we go through the process of making sure that that chemical is not used; isn't that right?

Mr. **Meyerhoff**. Well, we have a regulatory system that we are now trying to work out that will prevent that contamination.

We have a town in California not too far from where I live where 11 children have been found to have 9 different kinds of cancers. The town—McFarland is its name—has less than 6,000 people. Two of the children have died already; three live on the same street. The cancers include leukemia, brain tumors, lymphoma—the last of which killed a 4-year-old. It is not certain what caused those cancers, but if it was the ground water as is suspected, I do not believe that FIFRA should prohibit the mothers of those children or the parents of those children from seeking whatever legal recourse the current tort system provides.

Senator **Melcher**. I am familiar with the examples you have given, and I am familiar with a lot more where ground water has created a significant health hazard. I definitely think this is one of the issues. What is this label supposed to do? Who does it protect? It certainly seems to me that you have got the farmers right in the middle.

Mr. **Meyerhoff**. I think the final solution is to find a provision of FIFRA, which I think is pivotal to these amendments, that will put in place a regulatory system that will ensure that ground water will not be contaminated in the first instance. And that will require specific and effective steps to be taken when contamination is found to prevent its exacerbation; it strikes me that is the way to go.

Senator **Melcher**. Thank you.

Thank you, Mr. Chairman.

Senator **Lugar**. Thank you, Senator Melcher, and I thank you all for coming and for waiting through this morning's witnesses and offering your testimony. We look forward to working with you on this.

The hearing will recess until 2 o'clock this afternoon, when we will hear additional witnesses.

[Whereupon, at 12:05 p.m., the committee recessed, to reconvene at 2 p.m., this same day.]

[Whereupon, at 2:12 p.m., the committee reconvened, Hon. Richard G. Lugar, presiding.]

Senator LUGAR. This hearing of the Senate Agriculture Committee will now come to order.

We will proceed with this hearing on the Federal Insecticide, Fungicide, and Rodenticide Act and call a panel of Mark Maslyn, assistant director, National Affairs Division, American Farm Bureau Federation, Washington, DC; Ron D. White, consultant to the Texas State Department of Agriculture, in Austin, TX.

We appreciate both of you coming, and we would ask that you make either short statements, or summarize your testimony, so that we may proceed with questions.

You may or may not have heard the testimony of this morning, but we have already gauged the intentions of EPA, the Department of Agriculture, and a coalition of persons involved with the National Chemical Association and the Public Citizens' Congress Watch and the Natural Resources Defense Council. Later today, we will hear from an additional public witness.

So we are delighted that you are here, and would you please proceed with your testimony.

STATEMENT OF MARK A. MASLYN, ASSISTANT DIRECTOR, NATIONAL AFFAIRS DIVISION, AMERICAN FARM BUREAU FEDERATION

Mr. MASLYN. Thank you, Senator.

My name is Mark Maslyn. We appreciate the opportunity to be here today to share with you Farm Bureau's comments and suggestions on various proposals to amend FIFRA.[11]

The American Farm Bureau Federation is a general farm organization in 49 States and Puerto Rico. Membership of Farm Bureau includes producers of nearly every crop grown and harvested commercially in the United States.

Farm Bureau earnestly hopes that Congress will be able to pass a multiyear FIFRA reauthorization in 1986. We recognize the need for some changes in FIFRA and have participated in efforts to resolve differences between interested parties prior to congressional hearings.

Like the National Agricultural Chemicals Association, Farm Bureau and other representatives of the pesticide user community have been meeting with the Coalition for Pesticide Reform for much of the past year. We view this effort as a constructive attempt to augment the normal legislative process and increase the likelihood of a multiyear FIFRA package in 1986. It is my sincere hope that these negotiations will continue and that an agreement can be reached in several areas within the next few weeks.

In our review of S. 2215, most of the provisions are acceptable and will have little impact on agricultural producers. However, there are several provisions that we believe may have a detrimental effect on agriculture, either by increasing the cost of the pesticide product, or in someway affecting the availability of these products to farmers and ranchers. Of particular concern are the effects that these provisions could have on producers of so-called minor crops.

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[11] See p. 172 for the prepared statement of Mr. Maslyn.

We are concerned over the establishment of reregistration fees. These fees, totaling $150,000 per active ingredient, are apparently intended for use by the Agency to hire additional staff to comply with the expedited reregistration schedule. These fees, which will total $70 million, will undoubtedly be passed along, driving up production costs to farmers and ranchers and further eroding net farm income.

In addition, they set a potentially onerous precedent of user fees for agricultural chemicals.

Our concern, however, extends beyond the prospect of higher priced products. We believe that the combined effects of an expedited and rigid reregistration schedule, and the additional requirement of fees could hasten the removal of some products from the marketplace, leaving farmers without adequate means to protect their crop investments.

From the standpoint of farmers and ranchers, one of the most pressing needs in FIFRA is to afford a measure of protection from liability to individuals who conscientiously adhere to federally approved label directions, employ generally accepted farming practices, adhere to the recommendations of USDA extension service, and demonstrate their proficiency through training and certification programs.

At the heart of liability protection is the question of fairness, but beyond that, it just makes good sense from the environmental standpoint to provide that added incentive to farmers and ranchers who can demonstrate that they have used the product according to Federal label guidelines.

Farm Bureau is also very much opposed to including in FIFRA any citizen suit provision or private right of action. Such a provision would in the very least result in the harassment of farmers through nuisance suits alleging violations of FIFRA in the course of normal farming practices. If there are enforcement problems, either with EPA or in the State-contracted agencies, they ought to be dealt with directly to ensure that FIFRA is in fact an effective statute. However, permitting every individual to become a de facto enforcement officer is not the correct solution.

Finally, the issue of ground water protection is a rapidly emerging issue which will undoubtedly be in the forefront of discussion for some time to come. Farmers and ranchers who are served overwhelmingly by private wells in rural areas have much to be concerned with from the standpoint of both health and safety as well as potential restriction and limitations on land use practices.

We recognize that the ground water issue has to be addressed, but we are concerned from an agricultural standpoint that it must be addressed in a practical and realistic manner.

We support the idea of addressing ground water in FIFRA and are working with the Coalition for Pesticide Reform and the National Agricultural Chemicals Association in an effort to develop a mutually acceptable proposal.

Mr. Chairman, let me restate our support for a FIFRA package this year and our intention to work with you and members of the committee to ensure that this product is both effective and fair to all interested parties.

Thank you.

Senator LUGAR. Thank you.

Mr. White.

STATEMENT OF RON D. WHITE, CONSULTANT TO THE TEXAS STATE DEPARTMENT OF AGRICULTURE, AUSTIN, TX

Mr. WHITE. Thank you very much, Senator.

My name is Ron White, and I am here on behalf of the Texas Commissioner of Agriculture, to tell you why we think this bill will make it easier for States to do their part in pesticide regulations.

I would like to make a very brief summary statement and then answer any questions that you might have and try to address a couple of questions that were asked this morning—I did hear all the testimony this morning.[12]

For the last 3 years, I have been managing the regulatory program at the Texas Department of Agriculture. We have made some important strides down there on pesticides, and I am real happy to be here today, and I hope I can help.

I want to say very plainly that we have an opportunity here to pass a bill, which is a bill that has been agreed to by a coalition as you have described it, and I think we cannot let that opportunity escape. I really think it is important that we pass this bill.

We have a significant problem, and we have a significant amount of agreement about what the bill ought to do, and I think we really need to do it.

The most important thing that the bill does from my perspective is the reregistration of the old pesticides.

I think it is important here to say where I differ a little bit from some of the testimony that you have heard. I think we need deadlines. I think they have to be realistic deadlines, but I think we need deadlines.

The reason I think we need deadlines in there is because the existence of a deadline that is reasonable is the link to the budget. In this town, you do not get money for important things so nearly as you get them for urgent things. I think it is very important that we, being convinced of the importance of it, put some urgency in there for them. I know the EPA does not necessarily agree with that, and other people do not necessarily like those deadlines, but I think they are very important. Having watched the budget process, I think it is very important to put those in there.

There are some other budget points I would like to make later, but I think getting those products tested as soon as we can, and that reregistration process behind us is one thing that we can do. Until that is done, EPA cannot develop a ground water monitoring strategy because they do not know which pesticides are the most important targets, which ones are really likely to end up in the ground water somewhere, until they have been tested. There are lots of things that cannot go on until that is done. The testing of those products is just logically prior to a good number of things, including State enforcement. We do not have an ability, really, to develop a good strategy for State enforcement of FIFRA without knowledge about which of those products can cause certain kinds of problems.

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[12] See p. 173 for the prepared statement of Mr. White.

Some things have been said about the loss of products as we go through the reregistration. I really do not think that is a concern. I would agree with EPA, and I would agree with NACA, that I do not think you are going to see a loss of protection. You may lose some products, but I do not think you are going to see a loss of protection for farmers' crops. We have looked at that issue very, very hard, and I really agree with Jack Moore about that. If the Department of Agriculture or anyone else is really concerned about the loss of pesticides, especially for minor crops, the best thing they can do, the best thing the USDA could do would be to stop sending a budget up here that has zero in it for IR-4 programs.

If they are really concerned about that, they would not send that kind of a budget up here. But the budget, when it arrives at the Hill, has zero for IR-4. And if they are concerned, I think coming out with a strengthened IR-4 program would be the place to start, rather than to say that they are worried about the testing of these things.

The second thing that the bill would do would be to deal with inerts. We have come to find out over the last few years that inert does not mean benign, and we are finding some serious problems with inert ingredients. There is a good history of that, and I am real proud to see us starting to deal with that issue.

I think the community's right to know is an important issue, and I am glad it is in there.

I think another issue I would like to address momentarily is the importation of crops which have been treated with pesticides that are now banned in the United States. There was some discussion about that this morning. I can tell you for sure DDT is legal to use in Mexico, for example, on cabbage that comes in through Texas.

It is not legal in the United States, and it is not fair to Texas farmers to have to put up with that. In the name of common sense and equal treatment, we should not have to put up with that. I think dealing with that in a very straightforward fashion as you do in this bill is an important step forward.

I think having done all these things, I do not believe that you are going to shift any significant cost to the farmer; I really do not. I have heard other testimony to the contrary, but when I see that amount of money spread over that amount of acres, or that number of crops, it is pretty clear that you are talking about, on a per-acre or a per-crop basis, a very small amount.

I was present over on the House side when they were considering this, and Chairman Bedell sat right there and figured it out as to what it would cost the average farmer, and it is a trivial amount of money; it is very trivial. No one can estimate his production costs nearly so closely as to include that cost in it. It really does not matter.

In addition, there are benefits to the farmers. It is not just that they are laying out a cost, but there are benefits to farmers and to the rest of us from this sort of thing. So I am not concerned about shifting any large economic burden to the farmers as a result of this.

We have a very serious problem here. The World Health Organization estimates that there are half a million people annually injured, affected by pesticides, and 5,000 die. Those are their numbers. If we had that kind of a problem on terrorism or from any other cause, we would be doing something about it. So I am real pleased to see the attention of the Congress, both Houses, focused on this problem, and I think with this bill and with the agreement we have, we can go forward and really do something about it.

Thank you very much.

Senator LUGAR. Thank you very much, Mr. White.

Let me ask these questions, and either one of you or both may want to comment. You both have commented with regard to the cost of new procedures for reregistration. This morning I recited the paragraph from the Farm Bureau testimony to the panel of witnesses to get their comments, so that we had some crosshatching back and forth of the witnesses before and after lunch.

Essentially, the panel this morning took the position that I gather Mr. White takes, that spaced over all of the crops and different applications, formulas, and what-have-you, the amount of money, even in the $150,000 amount that is being mentioned, becomes a very small factor; perhaps one that is hardly measurable in farm costs.

Now, leaving aside whether that is so or not, would either one of you want to comment on how resources are to be obtained for a more vigorous reregistration program. One course of action has been the bill that we have introduced.

Another, in a sense, was the proposal made by the distinguished Administrator of EPA this morning, Mr. Moore, when he talked about changing of the system, and in essence, the burden that would be placed on the registrants to furnish some assistance in that variety, which influences costs, I suppose, in different ways.

Mr. Maslyn, as you heard all of his testimony, how should this reregistration thing be financed and supported in a way that you think would have the least burden for the farmers?

Mr. MASLYN. Well, our major concern—I agree with you that the $70 million figure that is being used now, probably spread out over the number of years and number of acres treated, probably will not put anyone out of business—but it does open a door to pesticide product registration fees.

We have seen, just since this proposal has surfaced, discussion now shift away from reregistration fees and the Agency come out with proposals of greatly expanded user fees, with some Members in the House considering the idea of registration fees rather than reregistration fees.

It opens the door to product registration fees, which I think will have a much more detrimental effect on producers.

We are very concerned about the reregistration process; we support it. I share all of the concerns that Mr. White just said. As farmers and ranchers, we will stand to benefit from the knowledge and understanding that these products, once they have been reregistered, are indeed safe to use. How we do that is a difficult problem.

Mr. Thomas, the Administrator of EPA recently stated that pesticides were now the Agency's No. 1 priority. Presumably, they would be able to shift some resources around within the Agency to support that statement.

They have done approximately 127 active ingredients so far. I think we can work with the Agency and work with the other interested parties in trying to come up with some flexible system, either by drawing out the timetable, the use of fee waivers, or a more flexible system to address the problems.

Senator LUGAR. Mr. White, do you have any further comments?

Mr. WHITE. Yes; one of the suggestions that has been made, if I understand your question, whether or not the companies should be asked to get some of that registration data in order, I frankly have mixed emotions about that—which really does not help you very much. But it is of some concern to me when an agency starts saying that what are fundamentally their regulatory responsibilities ought to be assumed by anyone else; and in this case, suggesting that they really ought to be made by the industry that is being regulated. I find it amazing, frankly, that they would suggest that, because it is fundamentally their responsibility to do that, and that is why we have an EPA, is to regulate pesticides. I do not think it is fair, frankly, to ask companies to do that. That really is not their job. We have entrusted EPA with the responsibility of regulating pesticides in this country, and I do not think it is fair to ask the companies to go back and do that, to go back and put that data in shape.

Senator LUGAR. I do not really want to argue the brief of EPA, but just for the sake of the hearing record, as I understood what Mr. Moore was saying, it was that EPA has limited resources, and the regulatory function ought to be applied with the greatest vigor to the end product of this research, as opposed to all the more humble beginnings the collection of papers and the gaps and so forth, that might be done by others without denying the public interest. I am not demeaning it as a secretarial function or merely a collection process. It is much more, obviously. But I suppose it was interest in sharing—and a frank one—of points of view as to how a number of interested parties, whether it be farmers, or chemical companies or Government regulators or USDA people, might rearrange responsibilities in a way in which the public interest could be served without denegrating any one particular function.

I have no brief for any formula of this type, but I appreciate the flexibility of the parties in trying to think this through really out loud together during this process.

Mr. WHITE. I think that is really useful to try to think it through out loud together. But the details of it that they are really trying to shift over to the manufacturers, I think, are appropriate at EPA. Frankly, that is my assessment. EPA has been for some years now reducing their in-house scientific capability. It has been reduced at EPA. This is an opportunity for them to move in the opposite direction. I do not think it is at all good that they have closed down their labs. I do not think it is at all good that there are fewer scientific personnel at EPA. And I think most of the American people would agree with that assessment.

Senator LUGAR. Mr. Maslyn.

Mr. MASLYN. If I could add, I think the proposal by EPA makes pretty good sense. If they feel comfortable with having the registrants look through their files and submit the data that is missing and at the same time save the Agency money and staff time, it just makes good sense. Certainly, we do not want the fox guarding the henhouse, but these are tough times for everyone. We are looking at a fairly significant new proposal to establish fees, and if we could reduce those fees or eliminate the fees by having a registrant go through their data package and supply the information initially, we ought to consider it.

I guess I would raise a question. I look at the fees, the total of $70 million being used, and to my understanding, the whole Office of Pesticide Programs' budget is less than that.

Senator LUGAR. The testimony was about $60 million this morning, and, of course, there was also testimony that the $70 million might not be accurate if one considers the number of 420 ingredients, that would not be reregistered. Although the witnesses could not offer an estimate of how many would be left by the wayside, there was a feeling that some would be.

I would gather the $70 million came from applying 420 times $150,000, more or less, and rounding it upward. So that by the same token, if the 420 becomes smaller, and $150,000 may not be expended in all of these cases—there is some indication that it might not be—you would get a more modest sum.

But even then, it is roughly a doubling of the expense, which sort of squares the problem in another way. If this is not to be borne by the companies, I presume it has to be borne by EPA.

Now, you suggest that EPA might find this a higher priority and shift some of its resources. But it was not clear in a practical way that it could do that much shifting within the constraints of budgetary policy for EPA now. We are in that kind of a bind and this is why we are attempting to massage around some of these elements and get more testimony from the witnesses.

Let me pick up on a related problem to that, and that is can the registration fee in the judgment of either of you be modified in any way to protect the interest of the so-called minor-use crops? Have you given any thought to those kinds of modifications?

Mr. WHITE. My position is that there is no need to protect the interest of the minor-use crops. We have probably as many or more minor-use crops in Texas than anywhere in the country, and we have looked at this, and it is a matter of continuing concern to the Texas Department of Agriculture, the whole issue of minor crops and protection for them.

Senator LUGAR. For the sake of the record, Mr. White, could you give illustrations of minor crops in Texas, what sort of crops would fit this category?

Mr. WHITE. Well, the most minor crop, perhaps, is aloe vera. We have 95 percent of the U.S. acreage of aloe vera down in the valley. Nobody is ever going to get rich producing pesticides for use on aloe vera; I can assure you of that. Or, jalapeno peppers is something else we raise that is a minor crop.

And it turns out, as Steve Schatzow said this morning, that the products that are used on aloe vera or that are used on jalepeno peppers are also used on bell peppers; they are also used on other crops. There is no one who goes out and develops pesticides specifically for use on those crops. They use it on wheat, corn, tomatoes, something else, and they also then use it on aloe vera or jalapeno peppers or something like that.

So you really do not need to worry about it. Where you do need to worry about it is in the development of data for tolerances, and that is where the IR-4 Program comes in, and that is where, I think, it is disingenuous for the USDA to come up here and holler about minor crops when they have been requesting a zero budget for IR-4 for a number of years.

Mr. MASLYN. I think the problem from the standpoint of minor use is not in the fee, but as Ron said, the products are not registered with the idea of marketing to a minor use crop of fruit and vegetables, but they are spinoff registrations.

I think the fee is not the significant deterrent. Potentially, the decision on the part of the registrant to supply the data, the $1 or $2 million studies to reregister the active ingredient will cause more of an impact on minor uses than will the fees. The fees are rather insignificant in comparison to the total dollars spent.

To that extent, however, if you have an old product, an old active, that maybe was registered on corn initially, and you have since then seen a number of corn insecticides come on the market, that older product may no longer be used primarily—it is no longer a big seller for corn, but it has a number of spinoff registrations for small crops. A decision by a registrant not to pursue that active ingredient could have some impacts on minor uses.

Senator LUGAR. Would either of you agree that conditional registrations were obtained too easily in the past, and without submission of adequate health and safety data? Should the authority for conditional registrations be retained?

Mr. MASLYN. We think it should be retained. I am not going to disagree with prior claims that conditionals were perhaps misused. I think the Agency believes that. They have modified their proposals. They have greatly curtailed the number of conditionals. I do, however, think that their flexibility ought to be retained, that the NACA/CPR bill seeks to strike some language that ought to be retained, ought to at least give the Agency that flexibility to determine whether or not the data that is submitted is sufficient.

Mr. WHITE. I think the language in S. 2215 deals with that very well.

Senator LUGAR. What changes would either of you recommend for applicator certification and training programs, and why would you see the need for such changes?

Mr. MASLYN. First of all, we are very supportive of the training and certification programs, and, I think, we have seen an improvement in the caliber and quality of personnel handling the pesticide products in the last 10 or 11 years since we have had training and certification programs.

I think there is one problem that comes to mind most readily when I travel the country and talk to farmers out there and ask them about their training and certification programs. They seem to tell me that they really are not as effective as they might be, that perhaps they ought to be upgraded more frequently; the core material ought to be improved. I do not think they feel that they are getting their time's worth.

Senator **Lugar**. Mr. White.

Mr. **White**. EPA has just finished a major study of this question in cooperation with their State departments of agriculture and other groups, and that report is available, and I would recommend it.

It is very clear to me, having done this at the State level, that it is a resource-intensive operation. Any time you are out there really trying to train people, it takes money. It just plain takes money. If we want to do a better job of it, it is just going to take more money. However, it is going to take more than just more money. It is going to take upgrading and keeping your training material up to date, and having a routine recertification every 3 or 4 years, and we are moving toward that in Texas. But it does cost money to get out there and teach people the proper way to use the new chemicals and make sure that the training on the new equipment is up to date.

So it is primarily a resource, a money issue; after you make the decision that you want to do it, there are no great hurdles in the way, except having the money to carry it out.

Senator **Lugar**. I thank both of you gentlemen for your testimony and for answering questions so forthrightly. We appreciate the opportunity to continue to work with you as we prepare the legislation.

Mr. **White**. Thank you.

Mr. **Maslyn**. Thank you very much.

Senator **Lugar**. Thank you.

The Chair would now like to call Jay Feldman, the national coordinator of the National Coalition Against the Misuse of Pesticides, in Washington, DC.

Mr. Feldman, welcome to the hearing. Would you please proceed with your testimony?

STATEMENT OF JAY FELDMAN, NATIONAL COORDINATOR, NATIONAL COALITION AGAINST THE MISUSE OF PESTICIDES

Mr. **Feldman**. Thank you, Senator. I will summarize my statement.[13]

Senator **Lugar**. Your entire statement will be made a part of the record.

Mr. **Feldman**. I appreciate that.

The basic point that I would like to bring to you today is that we would like the committee, as we have suggested in the House, to address both sides of the pesticide safety equation in reauthorizing and reforming FIFRA.

One side of that equation is very effectively dealt with through S. 2215, we feel, in terms of improving the testing and regulation of pesticide ingredients. The other side of the question regulates pesticide user training, as you have just asked a question about, and enforcement of the law as well.

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[13] See p. 178 for the prepared statement of Mr. Feldman.

To address either side of the equation and not the other will result in unacceptable contamination and poisoning.

Earlier today, Dr. Moore talked about not giving the wrong signals to the public through the special review program. What I would like to suggest is that we reverse that and respond to the signals we are getting from the public.

I will bring up Dr. Burmeister's study at this time and present to you his findings, as well as some other findings, and request that that be put in the hearing record.[14]

Senator **LUGAR**. Thank you. It will be made a part of the record.

Mr. **FELDMAN**. Clearly, what signal this study is suggesting and other studies—I have included one from British Columbia on "Cancer and Aplastic Anemia in British Columbia Farmers," and I have also included a study on lung cancer and other causes of death among licensed pesticide applicators working on structural application—the signal we are getting here, Senator, is that the pesticide control system is not working; that in those areas where people are directly exposed to materials, they are experiencing a higher than national average rate. We urge that you consider this as impetus for moving ahead with S. 2215.

There are other indicators or signals, of course, coming directly from the public. A recent survey by the Food Marketing Institute indicated that 73 percent of those surveyed were very concerned about the serious health hazards associated with pesticide residues in foods, and this is 2 years after the EDB crisis with grain contaminated with that product. So that there is another signal in terms of a poll that indicates that there is clear reason to act.

My testimony sketches some of the other problems which have resulted, which again are signals, such as indoor exposure to pesticides, ground water contamination—that has been well documented—and a number of other problems that have resulted.

You are familiar, I am sure, as is everyone else, with the litany of incidents that we have seen on the front pages of our newspapers, such as the heptachlor contamination of milk, and the EDB contamination, which has been brought up.

A survey in New York documented that of those homes surveyed in the structural pest control area, of those homes surveyed, 32 percent had higher than acceptable levels of termiticide.

You probably remember the 1985 watermelon contamination with aldicarb.

The point here is that many of these problems are a function of misuse of pesticides. Many of the problems are a function of inadequately registered and regulated pesticides.

I have attached at the back one last signal which I will leave you with, and that is a poster that we found along the Great Lakes—this one happens to be in Michigan—in which there are explicit instructions on how to prepare a Great Lakes fish before you ingest it. The reason for this, as you see at the bottom there, is to decontaminate effectively those areas of the fish where the chemicals are storing themselves and to minimize exposure to the public.

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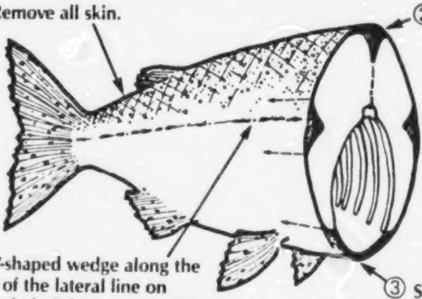
[14] The Burmeister report has been retained in the committee files.

Cleaning Great Lakes Fish



① Remove all skin.

② Cut away dorsal fat along backbone.

③ Slice off fat belly meat along bottom of fish.

④ Cut away a V-shaped wedge along the entire length of the lateral line on each side of whole fish or on skin side of each fillet.

Some Great Lakes fish are contaminated with low levels of toxic chemicals. You can minimize your intake of these chemicals by properly cleaning, trimming, and skinning your fish. Follow the four steps.

Cooking does not destroy chemicals but the heat from cooking melts the fat in the fish, removing some chemicals. Do not use fish drippings in anything meant to be eaten. Discard fish drippings in the garbage.

For more information, contact the Michigan Sea Grant College Program–University of Michigan, 2200 Bonisteel Blvd., Ann Arbor, MI 48109, or 334 Natural Resources Bldg., Michigan State University, East Lansing, MI 48824. University of Wisconsin Sea Grant Institute (1800 University Ave., Madison, WI 53705)

There are clearly pesticides indicated in this whole dilemma that you see in front of you. Toxafene is one clear example of a pesticide that shows up in fish.

If Senator Melcher were here, I would remind him of the incident a couple of years ago with contaminated game meat, in which the health department of Montana put out a similar warning to people to cut away the fat of the birds that were being fed.

Farmers, users of pesticides are caught in the middle of a crisis that we are seeing here, and our hope is that through S. 2215, we can minimize some of the problems that farmers encounter.

There are other things that farmers and users can do to minimize some of these problems, and we have listed for you here in the testimony a series of improvements that we feel need to address the user side of the equation.

Improve training and certification, which you have raised, to ensure that everyone who handles the chemical, whether it is out on the farm or in someone's home, has adequate training and has established his or her user competency; to establish recordkeeping; to control for drift, where we basically expose people off-target; to control special local need permits; to ensure that when a locality or a State has identified a special problem, that yes, they be able to respond to that problem with a particular pesticide or pest management strategy, but that there be some guidance and criteria established, which do not exist currently. So we see special local needs permits issued over 25 State areas for the same pesticides. Also, that we control for indoor exposure, as well, and that we establish a worker protection program for farmworkers to ensure a minimization of risk there, and an enforcement system.

The enforcement system in any law is critical to implementing the intent of Congress. So, clearly we need to establish one that provides for enforcement of this law.

What we are suggesting, and you have heard the Farm Bureau resist in their testimony, is a private right of action after an individual has exhausted administrative remedies. So that if I do not receive an adequate response from EPA in the State, I as a citizen, an aggrieved citizen, can approach the courts and ask for redress in that forum.

Finally, in addition to the ground water issue, which we are glad to see progress on, we want to urge you to carefully look at and resist attempts to curtail the ability of localities to establish notification provisions and get involved in what is happening around the country currently, the right to know what is being used, when it is being used.

The problems, the signals that I talked about earlier can be controlled. It is very hopeful, a very hopeful sign that there is agreement on a series of restrictions in the registration area. Let us move ahead on some of the user restrictions and make this a complete, comprehensive package, and make the Indiana Isaac Walton League and other environmental groups around the country happy about a package of amendments.

Thank you.

Senator Lugar. Thank you very much for your testimony.

Having read through the testimony, you raise a number of questions, but apparently endorse Senate bill 2215.

Mr. Feldman. Yes.

Senator Lugar. Then, do I gather that the additional comments that you have made after this endorsement are amendments that you believe ought to be offered, or are these areas that you think are touched upon in some fashion?

Mr. Feldman. No; what we are suggesting is that in developing a committee print, that you take as whole S. 2215, and that that be indicative of a tremendous amount of progress in the registration areas and many other areas, and that you couple with that a package, if you will, of amendments in the areas where we have outlined. This, we feel, will go a long way toward comprehensively dealing with the bottom line question, which is pesticide contamination or poisoning.

Senator Lugar. You have touched upon this issue, but just to make our hearing record complete, let me raise the question that if an applicator follows the instructions on the pesticide label carefully, why shouldn't that person be exempt from liability, without limited liability as a disincentive for the applicator to follow the label requirements carefully?

Mr. **Feldman**. Well, it may be a disincentive. The question is where does the chain of responsibility begin and end. There are a number of choices being made here, both by registrants and by users of pesticides.

First off, I would concur with others that raised the issue and responded to this question in the context of tort reform in general, and I would urge that the Congress look at this question in its totality and not piecemeal.

But to answer your question specifically, I do believe that any user of a material does bear some burden, especially from the view that we are handling products that are not necessarily safe overall. A pesticide registration label does not ensure that a product will not result in harm. So a user when using a federally registered product should never think that there may not be harm to himself or his family or the neighboring community.

It is a misconception to leave the user with the implication that as we see, many of the trade associations, even outside the District of Columbia, in literature being disseminated to the community, if you follow this pesticide label, or if you use an EPA-registered pesticide which has an EPA registration number at the bottom of the label, then your hands are clean, and that you do not have anything to worry about.

I think the judgment, given the risk benefit standard by which we are regulating pesticides, the judgment does lie with the individual user, and if there is a resulting contamination or a poisoning, that that user does play a critical role in that chain of responsibility.

Unfortunately, that is the case. That is why we are glad to see growers and users of pesticides taking much more seriously these days questions of integrated pest management and nonchemical approaches that might minimize exposure when possible.

Senator **Lugar**. On the State and local regulatory issue that we queried many witnesses about, if we are going to allow pesticides to be produced in this country, is there some merit in the argument that pesticide producers should not be expected to amend their business operations in order to satisfy the concerns of many local jurisdictions across the country that may decide to legislate in this area?

Mr. **Feldman**. As you can imagine, since we represent local people and community groups across the country, this is a priority and crucial issue for us. In fact, we just got finished with a merger debate on this very question in Annapolis, MD.

People feel very strongly at the local level—when you attend a city council meeting, or you sit in the deliberations on this question, they feel very strongly about their local police powers to take some level of control over their lives.

The issue of Ocean City has been raised to kind of exaggerate or, basically, bring this whole question into perspective. But beyond that kind of obtuse example, the local jurisdiction, when it comes to the use of a material or of a poison, feels that they do have some certain level of authority similar to zoning, where they can get involved and make some judgment as to what is in the best interest of their residents.

The police power that people—let me give you the example that is most prevalent across the country, and we are seeing in Michigan and Illinois and Ohio and California and Oregon and various States beyond that—the thing people feel most strongly about in those situations is the ability to notify when pesticides are being used—post a sign, notify through a piece of paper, indicate where pesticides are being used, and enable people to take precautions, so that they can avoid exposure. If there is a necessary reentry time, like do not let your kids out to play on the lawn, or take the toys in, or cover your car or move your car, whatever—there is a different sentiment wherever you go in these communities as to the most effective way to do that. But I will tell you, once people get into this, the similarities across State lines is mind boggling. People are looking for simple signs, simple notification.

Even in the State of Maryland, we are not finding many discrepancies across this case. I think we need to wait on this one and watch what is going to happen in Maryland this spring, where we had the biggest counties in terms of population in the State, Prince Georges County and Montgomery County, having instituted a notification scheme and basically use this type of authority.

I do not think it is going to be the problem that your question implies. I think there are some standard operations, and the bottom line is that when you get down there at the local level and talk to the local elected officials, this is a hot one for them, and they basically are very interested in maintaining their authority in these areas.

I think you will find that in Indiana, as well.

Senator **Lugar**. What would you say to the testimony we received from one individual, that one way of managing this problem is to allow State governments to survey local activities, and in the event the local motion seems far out of line, for States to have the power to rescind those?

It is, I suppose, a fairly common principle of American federalism that many local jurisdictions derive their powers from the States, in the same way the States cede authority to the Federal Government.

Mr. **Feldman**. I think you put your finger on the answer. Currently, States do just that with the pesticide law and try to establish uniformity. In the case of Maryland, when the State debated the question of preempting the local jurisdictions, they decided against it.

So that different States will come out differently on this question, and I think you are suggesting the reasonable solution—allowing States to deal with the problem as they see fit.

Senator **Lugar**. Mr. Feldman, we thank you very much for your testimony, and for your answers to these questions.

Mr. **Feldman**. You are very welcome. Thank you.

Senator **Lugar**. This will conclude our hearing for this afternoon, and we appreciate everybody coming to hear the testimony.

[Whereupon, at 3 p.m., the committee recessed, to reconvene, at 10 a.m., Wednesday, April 30, 1986, in room SR-332, Russell Senate Office Building.]

TO AMEND THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

WEDNESDAY, APRIL 30, 1986

U.S. Senate,
Committee on Agriculture, Nutrition, and Forestry,
Washington, DC.

The committee met at 10 a.m., in room SR-332, Russell Senate Office Building, Hon. Jesse Helms (chairman of the committee) presiding.

Present: Senators Helms, Dole, Lugar, Cochran, Boschwitz, Hawkins, Andrews, Wilson, McConnell, Zorinsky, Leahy, Melcher, Boren, Pryor, Dixon, Heflin, and Harkin.

STATEMENT OF HON. JESSE HELMS, A U.S. SENATOR FROM NORTH CAROLINA

The Chairman. The committee will come to order.

Today we continue the hearings related to the reauthorization of the Federal Insecticide, Fungicide, and Rodenticide Act.

My wife asked me what I was going to do today, you know, of any consequence to the Republic, and I told her I was going to preside over a FIFRA hearing. She said what? And I spelled it out, and she said, "I still don't know what you're talking about."

But this is a very important subject. It is important to everybody, whether or not they know it is important.

Senator Lugar chaired the first day of hearings on this subject last week. I was present for much of the time. The committee heard many eloquent statements from industry and environmental witnesses, as well as the EPA and the Department of Agriculture.

We have a long list of witnesses today and I have therefore requested that the witnesses limit their oral statements, as much as possible, to 5 minutes with the understanding that their full written statement will be made a part of the record, and thereby available to the members of the committee, other Senators, and the staff of Senators. I look forward to a thorough hearing on these complex issues, and I am grateful to each of you for the time that you have devoted in preparing your testimony, and coming here to be with us. Senator Dixon.

Senator Dixon. Mr. Chairman, thank you. I have a brief statement which I would ask be made part of the record.[1]

The Chairman. All right. Without objection, that will be done.

The first panel consists of Ralph Engel, president of the Chemical Specialties Manufacturers Association, accompanied by Dr.

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[1] See p. 188 for the prepared statement of Senator Dixon.

Warren E. Stickle, director of legislative affairs. You gentlemen will take the first two seats.

Then Harvey Gold, executive vice president of the National Pest Control Association of Dunn Loring, VA.

Next will be Earle K. Borman, Jr., vice president of Sterling Drug Inc. of New York. And last, but certainly not least, Robert M. Russell, vice president of government relations, Orkin Pest Control, Atlanta, GA.

Gentlemen, thank you very much. I know it is an imposition to come to Washington and prepare testimony, and sometimes people say, well, it does not do any good, but, really, it does, and I appreciate the citizenship involved in it. You may proceed in the order that you appear here at the table.

STATEMENT OF RALPH ENGEL, PRESIDENT, CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION, ACCOMPANIED BY DR. WARREN E. STICKLE, DIRECTOR OF LEGISLATIVE AFFAIRS

Mr. ENGEL. Good morning, Mr. Chairman.

The CHAIRMAN. Good morning, sir.

Mr. ENGEL. My name is Ralph Engel and I am president of the Chemical Specialties Manufacturers Association, or CSMA, and I am accompanied today by Dr. Warren Stickle, on my left.[2]

He is director of legislative affairs at CSMA. The association has a membership of more than 400 firms, and specifically represents the nonagricultural pesticide industry including disinfectants and sanitizers, home, lawn, and garden pesticides, and a wide variety of other pesticides for home, industrial, and institutional use.

We applaud you, Mr. Chairman, for introducing S. 2346, the Pesticide Reform Act of 1986, a bill that reflects the interests and concerns of many agricultural and food groups, farm organizations, rural and urban pesticide-user groups, and other manufacturers. We support this legislation.

We have a number of concerns with the bill that was introduced earlier, S. 2215, and we will just touch on a few of these in the interest of brevity.

With regard to reregistration timetables, nearly everyone agrees that the present EPA reregistration program is moving too slowly. Conversely, S. 2215 provides that the total reregistration process be completed within 6½ years. We believe this timetable is unrealistic.

On the other hand the Agency can complete the reregistration process in 9 to 10 years. If the registrants help by identifying data gaps, if the list of data gaps is released in a staggered process over 3 years, and if the data are processed over 3 years, the Agency would be able to spread out its manpower and resources.

With regard to reregistration fees, pesticides should not be singled out for special user fees when other preclearance statutes are specifically exempt from user fees or registration fees.

The Congress has consistently taken steps to prohibit user fees for the registration of drugs, thus setting a clear precedent. S. 2215, however, calls for a one-time fee of $50,000 for each active ingredient registered for use on food or feed, so that the Administrator can compile a list identifying data requirements. It also states that the Administrator shall collect an additional one-time fee of $100,000 from the registrant or registrants, for each active ingredient for use on food or feed to be reregistered, so that the Administrator may accomplish the subsequent data evaluation.

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[2] See p. 191 for the prepared statement of Mr. Engel.

We support S. 2346 because it contains no proposal for reregistration fees. Mr. Chairman, many CSMA manufacturers produce disinfectants and sanitizers known as antimicrobial products. Registered under FIFRA, these products contain active ingredients for home, institutional, and dairy farm use and are used in the cleaning and sanitizing of laundry supplies, medical equipment, laboratory facilities milking equipment, and the like.

Some manufacturers register between 20 and 35 ingredients for antimicrobial products, each with a different use and a different EPA registration number.

Under language incorporated in S. 2215, each one of the approximately 300 individually registered antimicrobial active ingredients would be assessed a reregistration fee of at least $75,000, and likely up to $150,000 per registration.

Many small manufacturers will face a potential fee of up to $150,000 on each of the active ingredients they have registered. An amount that could represent a large percent of the company's annual gross sales, likely 10 percent. A recent preliminary assessment concluded that based on the production and distribution of some 350 million pounds of active ingredients, some 21 disinfectants, or about 15 percent of all antimicrobial products could afford a full chronic test battery.

Thus the impacts on the industry appears to be substantial. Between 60 and 85 percent of the active ingredients would drop out of the market or apply for data waivers based on economics, if it was available. This group represents a very small portion of the active ingredients, about 2 percent.

These reregistration fees will in fact control which antimicrobial products will be available in the marketplace. In our judgment, fees should not determine the availability of products.

Discussing inert ingredients for a few minutes. Recently, the EPA has substantially increased its interest in inert ingredients.

We support the Agency's efforts to focus its attention on those inert substances that are most likely to cause health problems.

And although we share the NACA-CPR and EPA concerns that the Agency ought to address these troublesome, inert ingredients, causing an end-use pesticide to be a hazard to man or the environment, we differ with the approach taken in S. 2215. We disagree that widespread exposure should, alone, be a trigger to the listing of inert ingredients, thus requiring additional testing. An inert ingredient should be listed only if a risk assessment, or hazard evaluation indicates a significant hazard may exist in the use of pesticide products.

With regard to labeling of inerts, we share the NACA-CPR concerns that troublesome inerts should be placed on the label if they cause an end-use pesticide to create a hazard to man or to the environment.

We suggest, however, that if a list is to be developed, the list be based on a risk assessment or hazard evaluation to see if a significant hazard exists.

We request that a ceiling be placed on the number of listed inerts, 50, but no floor, so that the Administrator can address any inert he feels is troublesome, without having to process 1,200 or more over the next decade.

We suggest that the requests for additional data on inerts be restricted to the Administrator's existing authority. Now although we share some of the concerns in the NACA-CPR proposal, or in S. 2215, we believe there should be a broader, more comprehensible alternative package to FIFRA amendments.

The NACA-CPR proposal is more narrowly focused on registration issues and reflects the thoughts of only a portion of the pesticide industry. Mr. Chairman, if we are to seek a 4- or 5-year FIFRA reauthorization, we need to address FIFRA in the broadest possible terms, attempting to reach out to the concerns of all groups and organizations.

We need to offer constructive alternatives, and to enhance, not impede, the legislative process. We respectfully ask your support in seeking a broader, more comprehensive alternative FIFRA package, that represents a broad compromise and establishes a consensus among many concerned groups and organizations.

Specifically, we urge this committee to support S. 2346. We at CSMA are committed to working with the committee to help resolve these important concerns and to improve the prospects for passing FIFRA legislation this year.

Thank you very much, sir.

The CHAIRMAN. Thank you, Mr. Engel. All right. Mr. Gold. Thank you very much. You may proceed.

STATEMENT OF HARVEY S. GOLD, EXECUTIVE VICE PRESIDENT, NATIONAL PEST CONTROL ASSOCIATION, INC., DUNN LORING, VA

Mr. GOLD. Thank you, Senator Helms. My name is Harvey S. Gold.[3] I am executive vice president of the National Pest Control Association which is the national membership association of structural, general household, industrial, and institutional pest control companies in the United States, consisting of about 2,300 member companies, all users of pesticides.

We are here in support of S. 2346 which contains those provisions that are of importance to the members of the National Pest Control Association.

I would like to mention, very briefly, that the National Pest Control Association's technical competence in research, education, and training in the use of pesticides, and in the production of a wide variety of educational and training materials has international recognition, and our educational materials are referenced and suggested by both Federal and State regulatory agencies for the training of pest control operators, to ensure the safe and effective control of pests.

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[3] See p. 206 for the prepared statement of Mr. Gold.

Currently, about 95 percent of the pesticides used by our industry are in the nonrestrictive or general use category. We are pleased to note that compliance with the label instructions has resulted, year after year, in a very high rate of safety, especially in view of the outstanding number of pesticide applications made each year. Senator, we favor the proposals in S. 2346, and what I would like to do is just highlight those provisions that are of interest to the National Pest Control Association.

One of these is in the area of certification, training, and recordkeeping. We are recommending the expansion of the area of education and training to provide for updated training requirements for both certified applicators and the noncertified commercial applicators who work under the supervision of certified applicators.

What this would do would be to set minimum passing percents for testing in the applicator tests. It would also require field experience that would not exceed 2 years for eligibility for certification as a commercial applicator.

It would require verification to a State agency of the successful completion of training for technicians who work under the supervision of certified applicators, and it would require registration of noncertified applicators with the State lead agency, so that they would have the capability of identifying and monitoring all commercial applicators in the State.

Another provision that would be added would be the certification of enforcement personnel, so that that would ensure that enforcement personnel are competent in the category where they have enforcement responsibility. We also would like to see the provision for recordkeeping, so that the quantities of pesticides can be monitored where and by whom they are used.

Under the section regarding label use, we believe there are two areas that need change, and these are covered in S. 2346, and one is a provision that would define the liability of those who can prove that they obeyed the pesticide label and this section would add an amendment that would establish that the applicator has exercised the proper standard of care if he can prove compliance with the FIFRA label.

But on the other hand, there are penalties that will—or actually, it would double the penalty that now exists. Another area that we are concerned with is that in the area of State primacy.

During the 1980's, a number of political subdivisions in different States, such as cities, counties, and townships, have attempted to exercise the same regulatory authority as the State, and we support the adoption, in section 24(a), of the existing law, of an amendment to solve the growing problem of this pesticide regulation by political subdivisions within a State.

This clarification would not pose any threat to the needs of local jurisdictions of Government. If a town or a county wished to have certain pesticide use eliminated completely, or between certain hours, they need only petition the State regulatory agency, and this decision, or approval for this decision should be forthcoming, if, for example, it does not endanger the State's ability to control disease vectors like mosquitoes, or rodents, or otherwise pose a health threat to the entire State population.

In the area of public right to know, we support the concept of sharing information with the public, and we believe, as is described in S. 2346, that this can best be obtained by providing information through material safety data sheets [MSDS], through State agencies, and through distributors, and not through EPA. Distributing the MSDS as proposed in S. 2346 would be much more practical, and would save the Federal Government considerable money because they would not have to distribute the substantial paper that would have to be distributed because of the registration of approximately 65,000 products.

If each one had a three-page information sheet, the amount of paper would amount to the millions. This can be conducted much more practically on the State level.

Mr. Chairman, I would like to thank you for this opportunity to present our views on S. 2346 which we support, and I would be pleased to respond to any questions that you may have.

The CHAIRMAN. Thank you very much. I was just thinking of the enormous amount of work that has gone into these statements, and sometimes I know the witnesses say: "Well, what's the point in my coming down here and doing all of this?" Well, the point is that this is not just like a ship passing in the night. Your words will be studied and reviewed, both by the Senators and the staff, and again, I thank each of you. Mr. Borman, we welcome you for Senator Zorinsky, the distinguished ranking member of this committee from Nebraska. You may proceed, sir.

STATEMENT OF EARLE K. BORMAN, JR., VICE PRESIDENT, STERLING DRUGS, INC., NEW YORK, NY

Mr. BORMAN. Good morning, Mr. Chairman, members of the committee. I am Earle K. Borman, Jr., a vice president of Sterling Drug, Inc., on whose behalf I appear here today.[4]

I am very pleased to have the opportunity to present Sterling's views on S. 2215 and S. 2346, two bills to amend FIFRA.

Sterling has a keen interest in the pending FIFRA amendments. Over 100 of our products we produce and market are registered under FIFRA. These products, with one exception, are not pesticides registered for major agricultural application on food and feed crops, although we do produce some house and garden pesticides.

Indeed, while some of the active ingredients in major agricultural use are often used in home garden pesticides, the concentration levels in the major agricultural applications are from 10 to 45 times greater. A large number of our registered products are disinfectants and sanitizers used in homes, institutions, including hospitals.

The active ingredients of these products are called antimicrobial agents. They kill disease-causing germs like staph and strep, and viruses that cause influenza and herpes.

The most familiar of these products, at least I hope you recognize, is Lysol brand disinfectant spray. Other examples of such products, although not produced by Sterling are Comet cleanser and Chlorox bleach. Approximately 300 such antimicrobial active ingredients are destined for reregistration.

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[4] See p. 212 for the prepared statement of Mr. Borman with accompanying material of Sterling Drug, Inc.

Neither bill before the committee adequately addresses the regulation of these products under FIFRA. Sterling has absolutely no dispute with those provisions of S. 2215 which address the major agricultural application pesticides.

We are, however, strongly opposed to, first, including antimicrobial and domestic application agents in a reregistration scheme designed for the major agricultural pesticides; second, reregistration fees; third, a mandatory system requiring EPA to study and regulate all or most inert ingredients used in pesticides; and, fourth, liberalizing access to confidential business information.

If FIFRA is to be amended, as proposed, we believe that Congress should limit those amendments to the major agricultural application pesticides. After all, that is the portion of the pesticide industry which has historically been the focus of most concerns.

It is also the only part of the industry involved in negotiating S. 2215. Our proposal could be accomplished by amendments regulating domestic application products and antimicrobial base products, like Lysol brand disinfectant, in a manner consistent with the inherently less toxic nature of the regulated products, and with the distinctive nature of this portion of the industry.

I would like to discuss these concerns, briefly, and have submitted for your committee's consideration, a more detailed discussion and analysis of these and other issues, along with some possible solutions.

On reregistration. We see the proposed reregistration bill as having a disproportionate and unfair impact on the domestic application/antimicrobial industry.

In EPA's current reregistration priority scheme, most of these antimicrobial active ingredients have a very low priority.

EPA's general priority list of active ingredients for reregistration is divided into 48 clusters; most antimicrobials rank 39th.

The reason is apparent: They are not of great concern. We do not hear of these products being canceled, and we do not read newspaper stories about their misuse, and some of these, such as Lysol brand disinfectant, have been in use for over 100 years.

The reregistration bill, nonetheless, will assess a minimum $75,000 admission fee for each of these active ingredients, regardless of toxicity.

This fee alone will deter many businesses from reregistering for economic reasons alone, and may well result in loss of valuable germ-killing products, especially in the relatively low-volume, hospital-use market.

EPA right now is in the process of designing a reregistration method for these antimicrobial active ingredients which appropriately accommodates agency information needs with the nature of the industry and the nature of the product.

EPA's flexibility in this area must be maintained. Please do not fix what is not broken. Limit the proposed amendments to those pesticides given priority in S. 2215.

Automatic reregistration is not appropriate for domestic application and antimicrobial products, many of which have been in safe usage for generations.

Congress should adopt a threshold test for reregistration of these products based upon a hazard evaluation which considers potential risk.

On inerts, S. 2215 contains a whole new regulatory program to require elaborate testing and data development plans for the great majority of the 1,200 inert ingredients used in pesticides today. Let me read you some of the inert ingredients in our Lysol brand of products. Color, water, cleaning agents, detergents, and grease-cutting agents.

Gentlemen, the idea of enacting a law that even permits FIFRA regulation of water is just plain silly. Moreover, given limited resources, it is an obvious misuse of those resources not to provide a priority threshold limiting the study under FIFRA to those inerts which current or future evidence indicates may very likely be harmful.

In addition, however, the inert review and proposed attendant labeling requirements present a serious long-term threat to formula confidentiality, which is the lifeblood of the disinfectant and sanitizer industry, and the house and garden pesticide industry.

A scheme to regulate inerts which requires the disclosure of the inert on the label, prior to any decision that the inert is actually hazardous is of grave concern to this industry.

Contrary to popular belief, reverse engineering the formula of a product when you do not know what its constituents are is very time consuming, difficult, expensive, and often impossible. It just is not done. However, once the constituents of the product are known, it is relatively easy to determine the formula through reverse engineering.

In any event, EPA already has a sound strategy for addressing inerts. We agree with EPA, the Audubon Society, and the environmental defense fund that the only change in the law necessary as to inerts is to specifically authorize EPA to require identification of a particular inert, after the inert has been determined to pose a hazard.

Sterling is also very concerned about two provisions in both bills regarding access to confidential and proprietary data; basically, trade secrets.

These are new provisions authorizing preregistration access to data on new active ingredients. Without belaboring the point, as I have stated previously, formula and new active ingredient information is the lifeblood of the domestic application/antimicrobial industry.

Expanding the universe of those persons given access to this information under FIFRA, particularly for new antimicrobial and domestic application active ingredients is, in our view, harmful.

At the very least this provision should be limited to authorize preregistration access only for new active ingredients for food and feed use.

In conclusion, as currently administered by EPA, there is, under FIFRA, first, an active and flexible reregistration program for antimicrobial products; second, a system for requiring data on inert ingredients which may pose a hazard, and third, safeguards for the protection of trade secrets.

In Sterling's view, no need has yet been demonstrated by anyone, at any hearings in the House, or before this committee, to alter EPA's present program. If there is any need, it is to address as soon as possible any food or feed chemical in major agricultural use which may now pose an unreasonable risk to human health or to the environment.

In no way is it necessary or even useful, however, to adopt a blunderbuss of procedure over substance, as NACA and some environmental groups would have Congress do.

Indeed, the truth has now been put on the record by Mr. Early of NACA, when he said to this very committee:

> The Patent Term Restoration issue has become intertwined with FIFRA. Part of our agreement with the CPR coalition includes removal of its opposition to moving Patent Term Restoration forward in tandem with this FIFRA package.

In short, Congress is being called upon by some in industry to revise the United States Code as to FIFRA purely and simply so that it will later be easier to enact some other wholly unrelated bill. We thank the committee for this opportunity to present the views of Sterling Drug, Inc.[5]

The CHAIRMAN. Thank you, sir. Our last witness on this panel is Mr. Russell.

STATEMENT OF ROBERT M. RUSSELL, VICE PRESIDENT, GOVERNMENT RELATIONS, ORKIN PEST CONTROL, ATLANTA, GA

Mr. RUSSELL. Thank you, Mr. Chairman. I am Robert Russell of Orkin Pest Control.[6] Our company is the world's largest in structural pest control. In contrast to agricultural pest control, our structural pest control service is rendered for commercial and residential properties for control of both household pests and wood-destroying organisms.

Our company operates in 43 States in this country, we employ some 5,000 people, and we serve over 1 million customers. We offer these comments for our company, for other conscientious users of pesticides, and on behalf of our employees and customers.

Pesticides used according to the label protect the food, the fiber, the structures, the health, and also the peace of mind of our Nation, and have done so with an outstanding safety record.

We would like to indicate to this committee the high efficiency and the safety of our structural pest control industry.

A Better Business Bureau summary for 1984, the latest summary available, shows structural pest control in 38th place in customer complaints. The total for structural pest control represents less than one-half of 1 percent of the total complaints in our Nation. We are way behind such widely known industries as automobile dealers, furniture stores, magazine sales, and others, which rank much higher.

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[5] COMMITTEE NOTE: Subsequent to the hearing on April 30, 1986, Sterling Drug, Inc., submitted a comparative summary and analysis of FIFRA (current law) and proposed amendments thereto. Because of the size of the document and printing cost considerations, the document will not be reproduced in the hearing record, but will be available in committee files for anyone wishing to view it.

[6] See p. 221 for the prepared statement of Mr. Russell.

An EPA report of 1983 attests to the benefits of termiticides for termite control and also comments to the safety of their use.

Another EPA task force report of 1985 attests to the efficiency of the certification programs being conducted in our States.

These unbiased reports speak to the efficiency of our structural pest control industry. Two California health reports show that of all of the urban pesticide accidents or incidents, only 3 percent were caused by the structural pest control industry. The other 97 percent were consumer related.

This, we believe, supports our industry's safe use of pesticides. Use of pesticides, which is increasing year by year, has no apparent detrimental effect upon the health of our Nation, for as pesticide use has increased annually, so has life expectancy, from 68.2 years in 1950 to 74.2 years in 1981.

I also wish to comment to the issue of whether to require certification of technicians as is now required for those who supervise commercial users of pesticides.

First, service technician and certified applicator represent two separate and distinct positions. To show the difference in required knowledge and skill at these two levels, our company position descriptions for the two positions are attached to the statement. We believe all or most other pest control companies would show an equivalent difference in the skills, the duties, and responsibilities of these two positions.

To require each position to be tested equally would result in one of only two probabilities. Either the standards for the certified applicator would be reduced—and this is counterproductive—or these standards would remain above the ability of the technician, and this, too, would be counterproductive.

If this technician becomes certified, this person will gain a title to his work position through the State certification process.

To replace such an individual for cause, we would have to have available a replacement with the State certification credentials or we would be unable to deliver the service to our customers pursuant to our contract agreements.

Thus our ability to supervise effectively is lessened by the necessity of meeting an external requirement.

We definitely support initial and continuous training of technicians as a superior alternative to certification testing. We have recommended mandatory training to EPA.

We believe this to be a first direction toward improved technician performance. Our industry is willing to change for improvement. We would ask that the change be within the existing structure of our industry and not a theoretical direction that might impair our efficiency.

S. 2346 speaks to this position and we support it. In conclusion, I would repeat that training, not universal certification, offers the best avenue for continued improvement.

We are equipped to furnish this training within our industry, through our national association, through our State associations, our suppliers, and our State officials.

I thank you for this opportunity to present my statement and will be happy to answer any questions that you might have, sir.

The **Chairman**. Thank you very much. Let me tell you the problem with trying to operate committees around this place. Senator Dole is not here because he is the majority leader and also he had to be at the Finance Committee this morning to work on the budget.

Senator Lugar, next ranking, is chairman of the Foreign Relations Committee. He is there, and not here, for the same reason I am here and he is not, because I am on the Foreign Relations Committee.

Senator Boschwitz is a member of the Foreign Relations Committee. Senator Zorinsky asked me to express his regrets that he had to go because he too is a member of the Foreign Relations Committee.[7]

You say, well, what is so important about the Foreign Relations Committee this morning? We are studying the essential problem of Embassy protection against terrorists, and it is almost a command performance. Frankly, I wish I could be at both places. But if we could have an understanding with this panel and subsequent ones, that the Senators may wish to submit questions in writing, I would appreciate your responding in that regard.

Senator Heflin has just arrived. We welcome him. We call him Judge around this place. This is the first panel and we have just had their testimony.

Let me ask a couple of questions, that I may myself, in the interest of time, forgo further questions, and submit them in writing.

I share the concern that Mr. Borman expressed about trade secrets. I do not think it is fair for the Government to make anybody disclose them, but I hope that we may persuade you, as I have been persuaded, that we are taking care of that.

Would you state what you told me about the safeguards on this thing. But I feel very strongly about that. I mean, a company spends millions of dollars, in many instances, to develop a product and then along comes big Government and says you have got to let everybody else know it and they cash in on it. We have got enough trouble with the Japanese on that, you know. Say for the record what you have just said, and then see if that is correct.

Mr. **Conner**. I believe, Mr. Borman, in both bills, the whole concept of industry-prepared summaries begins to unfold where the registrants themselves would actually prepare summaries of the registration data, health and safety data, this type of information, and then those summaries would be available to the general public. I believe there is some difference and Mr. Engel may care to comment, but I believe S. 2346 does provide maybe some stiffer penalties for misuse of that data, if the summary data did actually provide proprietary information to other people, that was misused somewhere in the process.

The **Chairman**. Let's leave it this way: If there are further suggestions about how this could be tightened up, we want to know it.

Mr. **Borman**. Could I make just one point, please, Mr. Chairman?

The **Chairman**. Yes, sir.

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[7] See p. 187 for the prepared statement of Senator Zorinsky.

Mr. Borman. And that gets back to my attempt in my comments to build a schism between the major agricultural use for food and feed, and others, however we might call them, home and garden, antimicrobials, and so forth. I think that the hazards are much different and the need for that public information is much different. Therefore, I tried to work in the comments, that if, directionally, you wanted to go for those which were the major concern, the major agricultural, or food and feed, which, I think, is the concern, why, that is fine, but do not, with the same brush, paint our types of products, where the need is different, and that was the point that I was trying to make.

The Chairman. I see. Now it was Mr. Gold who mentioned little subdivisions getting into the act. I know where you are coming from, and I say this to my friend from EPA, that everybody makes mistakes, and I do not say this with any hostility, but, we have an instance in Charlotte, NC, involving a relatively small company, that never heard a mumbly word from the EPA. The Mecklenburg County Environmental, whatever it is—it is an official function of the county government. They said, "You just find you're in court with the EPA, and all the rest of them, and all of a sudden EPA comes in and says, 'Oh, boy, you've been botching up the landscape here.' " And they say, "Well, why didn't you tell us?" I think it is going to be a reasonable defense with EPA because everybody wants to be reasonable.

It is tyrrany, if you do not know you are violating a law, and you have been told by a county. Now, I agree with you about that sort of thing. So I am just firing a little shot over the bow to EPA on this one. It is totally unrelated to what we are talking about, but it nevertheless is important. It is going to put this company out of business, and if I ever saw people operating in good faith, they have been. Do you have any further comment about that?

Mr. Gold. No, sir. We would just like to see you support it, and have it, once and for all, resolved, so that we can go on. Most of the members of our association are small businessmen, and having the multiplicity of regulations is a continuing burden, and we feel that if they can resolve things through the State, and, where appropriate, EPA, that it would make things better for everyone, and in the long run, allow our membership and the members of the structural pest control industry to provide better service because they can attend to what they have to do; and that is, to provide good pest control, instead of worrying about a wide variety of different regulations.

The Chairman. All right. Now let me raise one other question and I will let you go. At last week's hearings, which were conducted largely by Senator Lugar, the witnesses—at least most of them—including the Farm Bureau Federation, testified that the reregistration fee would not add significantly to the cost of a pesticide.

Why does CSMA so strongly oppose such a fee if this is indeed the case? Where else can the EPA obtain the estimated $60 million annual cost projected to be needed to carry out these changes?

Mr. Engel. Mr. Chairman, let me respond at least from our perspective.

The **Chairman**. This question is to everybody who wants to comment on it.

Mr. **Engel**. Sure. I direct you to a very narrow area, but a very important area, and that is the disinfectants and sanitizers market. Here we have some 300 active ingredients registered at EPA, and they vary, every single one of them vary, molecularly in structure, and have a different use. A large number of those, about 98 percent of the total, or 280 of the 300, are produced in very small quantities, 10,000 pounds, or in that area; but they have very specialized uses. They could not afford to go through a complete battery of testing and stay on the market. So they would all come off the market.

On the other hand, only some 21 of the 300 disinfectants, that are producing over 1 million pounds or more, could financially sustain the cost of testing.

They are active ingredients that we are talking about. They are not formulated products that we are referring to.

There could be some of these that have contact with food, in the cleansing of materials. These are important products for all of us from the perspective of health and safety, and yet we are setting a fee in motion that could remove 280 of the 300 from the market.

EPA itself has great concern about this very situation, and has been indeed working to see what uses each has, and to try and establish other mechanisms for testing these products, such as clustering them, where one could be tested to represent a whole class, or do tier testing where you do tests, and if they prove to be negative, you have to have some confidence that you do not have to do the whole battery.

We commend EPA for their efforts in trying to resolve this issue internally, because none of us want to see all these products go off the market.

But this very situation exists under this fee structure, and we are principally opposed to registration fees at CSMA, or reregistration fees as well, and think that such dollars ought to come out of general funds.

There are two preclearance statutes in this country. There is the Federal food and drug laws, and there are pesticide laws. Just last year, the whole process of registration fees went through Congress and they turned down a registration fee for drugs. We do not believe pesticides ought to be singled out for these reregistration fees when in fact they benefit society. It is not just a very small narrow spectrum of activity where, for example, you or I can go to a State or Federal park and pay a fee to use the Federal park for our personal use. These are benefiting society, and we think that indeed general funds ought to be used.

But again, the disinfectants are sorely hurting with regard to this process as proposed in S. 2215. Thank you, sir.

Mr. **Borman**. I would like to also comment, please, Mr. Chairman.

The **Chairman**. Yes, sir.

Mr. **Borman**. As Mr. Engel mentioned, there are 300 active ingredients. These are found in about 14,000 antimicrobial-formulated products. In many of these products, the antimicrobial is an ingredient in there which is not the main ingredient for the function of that product.

For instance there is a hospital disinfectant cleaner. Its main function may be to clean but you also want it to leave disinfection or sanitization in the hospital.

Therefore, the amount of active ingredient that is in that particular product is small, and again, on that subject, the so-called inerts have a tendency to be thought of as inactive; they are active for other functions. It is not like in some agricultural products where there are builders, and that type of thing in it, that is essential for the function ingredient. A toilet bowl cleaner, a bathroom cleaner, its function is to clean and you also want germs killed at the same time. We have about 280 ingredients of these, which are small volume, which are feeding these hospital products and home-use products, and those are the people that will go out of business with the fee basis.

The **Chairman**. We welcome Senator McConnell and Senator Harkin. Howell, any questions?

Senator **Heflin**. No.

The **Chairman**. Senator McConnell.

Senator **McConnell**. No.

The **Chairman**. Senator Harkin.

Senator **Harkin**. No, Senator.

The **Chairman**. I appreciate your coming, and as I said, as questions may occur to Senators present and absent, at a later time, then we will file those in writing. Thank you very much for your very instructive testimony, and we appreciate it, enormously.

The next panel includes Robert C. Keeney, vice president, government operations, and Claudia R. Fuquay, who is director of congressional relations, United Fresh Fruit and Vegetable Association, Alexandria, VA.

Then Lawrence T. Graham, executive vice president, National Food Processors Association, Washington, DC and, Clausen Ely, Jr., who is general counsel of the NFPA, Benjamin C. Bolusky, director of government affairs, American Association of Nurserymen, Washington, DC, and, Peter Hutt will be here shortly, representing the Grocery Manufacturers of America and he will be seated down there close to my friend from Kentucky.

We have, I would say to the Senators, that we have suggested that each witness try to limit his or her testimony to 5 minutes, so that we can expedite the rather long agenda that we have, with the understanding, of course, that your full statement will be printed in the record.

You may proceed, Mr. Keeney. May I suggest that would you not come up here so you can——

[Laughter.]

The **Chairman**. Well, you are just a small blur where you are sitting, and I know you have not lost that much weight, Howell. You may proceed, Mr. Keeney.

STATEMENT OF ROBERT C. KEENEY, VICE PRESIDENT, GOVERNMENT RELATIONS, ACCOMPANIED BY CLAUDIA R. FUQUAY, DIRECTOR, CONGRESSIONAL RELATIONS, UNITED FRESH FRUIT AND VEGETABLE ASSOCIATION, ALEXANDRIA, VA

Mr. KEENEY. Mr. Chairman, and members of the committee, my name is Robert Keeney, and I am vice president of government relations for United Fresh Fruit and Vegetable Association.[5]

With me today is Claudia Fuquay, director of congressional relations.

United is the national trade association for the fresh produce industry. We commend the chairman for taking such an active role in beginning discussions on FIFRA.

Although United generally supports certain provisions in S. 2215, we feel that a number of issues are better addressed in S. 2346, that you have recently introduced. These provisions center on the minor use issues, which are extremely important to my members, since chemical manufacturers and the EPA regard fruits and vegetables as minor crops.

Title III of S. 2215 addresses reregistration. Of concern to our industry are the proposed reregistration fees. We feel that pesticide registrations for minor crops should be exempt from these fees.

Any amendments to FIFRA should recognize the unique needs of producers of minor crops, as does title II of S. 2346, by allowing EPA some flexibility in the process.

Another area of concern with S. 2215 is in section 1007, "Tolerances for Agricultural Commodities." This section would require that within 60 days, the Administrator revoke or amend the tolerance of domestic or imported commodities if the registration of a pesticide "has been canceled, suspended, denied, or voluntarily withdrawn."

There are situations where pesticide registrations have been voluntarily withdrawn because of a lack of need by the agricultural community, or lack of economic incentive for the manufacturer.

If the United States starts revoking tolerances where there is no health problem, other countries might begin refusing to import U.S. agricultural commodities for the same reason.

The produce industry is having a difficult enough time exporting, without providing our trading partners with new means of retaliating. Second, we are quite concerned about the amendments in paragraphs (A) and (B). As written, this language amends the current Food, Drug, and Cosmetic Act, so that the FDA no longer has authority over section 408 or 409.

United is concerned as to the administrative delays that these six very short lines in S. 2215 could cause within the agencies.

Title XII—Employee Protection, also is of concern to this industry. Current U.S. labor laws protect employees from employer retaliation when the worker has, with just cause, filed complaints against growers.

We feel that the language in S. 2215 gives no protection to the employer for acts of harassment by workers and organizations representing workers.

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[5] See p. 225 for the prepared statement of Mr. Keeney.

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United would like to voice its support for three additional amendments that are contained in S. 2346. Currently, FIFRA prohibits the EPA Administrator from denying a registration simply because there is another pesticide already registered for use on the same crop against the same pest.

This prohibition should also apply to the States. We also support amendments contained in section 1701(a)(2), that would prohibit a State from setting residue tolerances different from those set by EPA.

Any residue tolerances set by the State that are different from those set by EPA creates chaos in interstate transport of agricultural commodities and becomes a barrier to trade.

And finally we support section 1003 of S. 2346, "Liability for Pesticide Use Damage." Our members are farmers, not scientists. They are dependent on accurate label information.

We believe that if the user follows the label, then, under no circumstances, should he be found negligent or liable.

Mr. Chairman, and members of the committee, I thank you for this opportunity to present our testimony and will be happy to answer any questions you may have.

The CHAIRMAN. Thank you very much, Mr. Keeney, for an excellent statement. You are just here to keep him straight; is that right?

Ms. FUQUAY. That is right.

[Questions submitted by Senator Wilson to United Fresh Fruit & Vegetable Association, and answers thereto:]

Question 1. Each of your statements expresses support for including a provision to assure national uniformity of tolerance levels in pesticides due to the problems resulting from inconsistent standards. By way of example, you mention EDB and daminozide. While the Committee is familiar with events surrounding EDB, it would appreciate receiving more specific data on the uses of daminozide, existing federal tolerances, the proposals being considered by Massachusetts, Maine and any other state that would result in a different standard, and the impact that such a state standard would have upon your members.

Answer. The current federal tolerance for residues of daminozide for raw and processed apple products is 30 ppm. EPA has proposed to lower that tolerance to 20 ppm since EPA lowered the application rate in January. The state of Massachusetts on May 13 adopted a much lower tolerance for daminozide of 5 ppm. A suit has been filed challenging the state action on the basis that federal law prohibits states from preempting federal bodies in setting tolerances, because such action places an unconstitutional burden on interstate commerce. It is expected that other states such as Maine will wait to see the outcome of this suit.

Question 2. Similarly, given that four different tolerance standards for EDB have existed for nearly two years, what has been the practical impact upon the businesses of your members. Does the situation impose additional costs upon your industries or their consumers and, if so, can you quantify them. Are there safety concerns which arise from differing state standards.

Answer. EDB is no longer used in the United States on fresh fruits and vegetables for domestic consumption. However, it is used for exports as required by the importing country in order to control fruit flies. We do not know of any cost study with national scope. But it has been estimated that enforcement of the Florida EDB tolerance of 1 ppm would cost the food industry between $25 and $50 million a year. Similar costs and dislocations would occur with differing standards in other states.

Question 3. Besides EDB and Daminozide, are you aware of any other food use chemicals which have more stringent state standards than existing federal tolerances. If so, would you pleased provide the Committee with a list of these chemicals, their uses, and the different federal and state tolerance levels. To ask the question differently, if Congress were to enact a pesticide uniformity provision, what specific food use chemicals, in addition to EDB and daminozide, and which states would be immediately affected.

Answer. Daminozide and EDB are the only agrichemicals currently subject to state residue limits different from EPA tolerances. However, a number of agrichemicals are under EPA review because of safety questions. We are very concerned that states may decide to set differing tolerances on these other chemicals.

The CHAIRMAN. Mr. Graham.

STATEMENT OF LAWRENCE T. GRAHAM, EXECUTIVE VICE PRESIDENT, NATIONAL FOOD PROCESSORS ASSOCIATION, ACCOMPANIED BY CLAUSEN ELY, JR., GENERAL COUNSEL

Mr. GRAHAM. Thank you, Mr. Chairman. I am Larry Graham. I am executive vice president of National Food Processors Association and I am accompanied by Clausen Ely, who is our counsel from Covington & Burling, in case I say anything wrong.

I appreciate this opportunity to present testimony today on FIFRA.[9]

The National Food Processors Association represents about 600 member companies that pack processed prepared fruits and vegetables, meat, fish, and other specialty products.

Also in our association are companies that provide equipment, supplies and services to the food industry. It is very important to our members that they have an abundant selection of high quality raw agricultural products for the manufacture of a wide variety of processed foods.

For this reason, FIFRA is a very important agriculture statute, not just to the farmer who depends on certain yields per acre, but also to the food processor who seeks safe and economical raw ingredients in his food products.

The bills S. 2215 and S. 2346 represent months of hard work and cooperation between diverse groups with varied interests, and we appreciate this. For reasons that I will discuss, we oppose certain provisions of S. 2215 and prefer the alternative S. 2346.

Initially, we are concerned that S. 2215 fails adequately to take into account the minor use pesticide needs. Many of our members rely upon minor use pesticides for production of a variety of fruit and vegetable products.

The general effect of the conditional registration and reregistration provisions of S. 2215 would be to make registration of new pesticide uses, and the maintenance of old uses, more difficult and expensive.

S. 2215 we think would restrict EPA authority conditionally to register new pesticide uses but would impose short and rigid timeframes for reregistration of old pesticides, and would substantially increase the costs of reregistration.

For these reasons, we support the alternative provisions in S. 2346 introduced by you, Senator Helms.

In our view, S. 2346 offers a more realistic reregistration timetable. It also would eliminate reregistration fees and would expressly provide EPA necessary discretion to alter data requirements, where appropriate.

We strongly support the provisions of S. 2346 that establish uniform national pesticide tolerances and prohibit State and local pesticide tolerances different from those established by EPA. Virtually all of our members grow, process, and market their food products on a multi-State or national basis. Multiple and consistent State and local pesticide tolerances frustrate EPA's attempt to set uniform national residue tolerances and disrupt interstate commerce.

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[9] See p. 227 for the prepared statement of Mr. Graham.

The need for a strong preemption provision of this kind has been confirmed by recent actions by the State of Massachusetts, and other local jurisdictions setting, or proposing to set, residue limits for EDB and daminozide different from those set by EPA.

We feel that only the Federal Government has the necessary resources, expertise, and broad perspective to gather and evaluate the relevant safety, residue, and economic data to determine appropriate national pesticide residue tolerances.

There should be only one standard for pesticide residues in food shipped in interstate commerce, and that standard should be established by EPA and not by 50 different States or thousands of local jurisdictions.

The establishment of uniform national tolerances would not, in any way, detract from the ability of State and local jurisdictions to vigorously enforce consistent tolerances.

Second, we support limitations on the rights of States and local jurisdictions to force reliance on a single or artificially limited number of pesticides. Section 3 of FIFRA prohibits the Administrator of EPA from denying reregistration of any pesticide simply because another pesticide is available, which is referred to, as you know, as a lack of essentiality.

We feel very strongly that FIFRA section 24 should be amended, as provided for in S. 2346, also to prohibit States from using lack of essentiality as the sole criterion in denying reregistration of a pesticide.

Alternative pesticides are essential for maximum flexibility in pest management programs, especially with the increasing resistance capabilities of pests.

A prohibition against use of lack of essentiality would assure that States register pesticides based on their own merits, but would not impair State authority to deny approval on other grounds.

Third, the food-processing industry must have the assurance that agricultural chemicals were used properly in the production of crops and ingredients.

With this in mind, we support provisions in S. 2346 calling for expanded and updated training and retraining programs for both certified and noncertified pesticide applicators.

Noncertified applicators, mixers and loaders, would be required to validate this training to the State, as is currently required of certified applicators.

Mr. Chairman, that concludes my testimony and I would be happy to answer any questions and thank you for the opportunity to appear.

[The following information was subsequently received by the committee:]

NATIONAL FOOD PROCESSORS ASSOCIATION,
Washington, DC, May 30, 1986.

Hon. JESSE HELMS,
U.S. Senate, Washington, DC.

DEAR SENATOR HELMS: On behalf of the National Food Processors Association, I am happy to offer responses to questions submitted to the Senate Agriculture Committee by Senator Wilson.

The use of pesticides in the production and post-harvest handling of raw agricultural commodities is an integral part of today's efficient agricultural system. Where the use of a pesticide results in a detectable residue in or on the raw agricultural commodity, tolerances are established by the appropriate Federal agency under the authority of the Federal Food, Drug, and Cosmetic Act. Such tolerances also apply to processed foods made from the commodity. Federally determined tolerances are fully effective and enforceable in every state. These federal tolerances facilitate the free movement of raw and processed foods among the states. NFPA, and other food groups, support the maintenance of national tolerance levels and, therefore, are backing the Helms' bill amendment to FIFRA disallowing states to institute their own tolerance levels.

The following answers give additional background information on our position.

(1) Daminozide is used on the following crops:

Peanuts.—Shortens vines, makes vines more erect and greener in color and increases yields.

Apples.—Assists in: (a) delaying maturity of fruit; (b) increasing red color; (c) preventing preharvest fruit drop; (d) maintaining fruit firmness and reducing of bruises during handling; (e) reducing fruit cracking; (f) helping control fruit size; (g) reducing vegetative growth on trees; and (h) promoting flower bud initiation. These attributes result in yield improvements and better market quality of fruit at harvest and/or after storage.

Pears.—May be used in Washington and Oregon only to control premature ripening and aid in preventing preharvest fruit drop, to promote flower bud initiation, to control vegetative growth of trees, and to assist in bringing trees into bearing.

Peaches and Nectarines.—Assists in improving fruit color, concentrating maturity, and hastening ripening.

Prunes.—For use in California only to hasten ripening on mature bearing trees.

Sour Cherries.—Improves color, hastens ripening, concentrates maturity, decreases fruit removal force thus reducing shaker damage, prevents late maturity fruit swell, produces a uniform firm cherry for improved pitting and grading, and reduces vegetative growth.

Sweet Cherries.—Hastens ripening, concentrates maturity and improves fruit color.

Grapes.—Increases berry set and reduces rate of vine growth.

Brussels Sprouts.—May be used on jade cross variety only in the state of California—promotes uniform sprout development.

Cantaloupes.—May be used only in Arizona and California to reduce vine growth.

Tomato Transplants.—May be used in states other than California on tomato plants before transplanting to retard stem elongation, to delay early fruiting, and to aid in concentrating maturity.

The following table shows the EPA tolerances for daminozide (40 CFR 180.246):

Commodity:	*Tolerance (PPM)*
Cherries—sour	55
Cherries—sweet	30
Apples	30
Peaches	30
Grapes	10
Nectarines	30
Pears	20
Peanuts	30
Tomatoes	40
Prunes	50
Brussels sprouts	20
Peanut hay	20
Peanut hulls	10
Melons	3
Pepper	1
Poultry kidney	2

Eggs, meat, fat, and meat by-products of cattle, goats, hogs, horses, poultry (except kidneys) and sheep	0.2
Milk	0.02

Attached is a copy of the new Massachusetts regulations regarding daminozide as adopted on May 13 by the Massachusetts Public Health Council. The new rule primarily affects apple growers and processors by requiring action levels in heat-processed apple sauce and juice products of 5 ppm by October 1, 1986; 1 ppm by October 1, 1987; and 0.01 ppm by October 1, 1988. These levels are considerably below the EPA tolerance level of 30 ppm for apples. EPA has proposed to lower their tolerance level to 20 ppm. NFPA concurs with the agency that a tolerance of 20 ppm is appropriate for apples grown under EPA's new use restrictions issued in January.

On May 20, NFPA joined the Processed Apples Institute, Inc., The International Apple Institute, and Uniroyal, Inc., in filing suit to prevent the Massachusetts Department of Public Health from implementing their new daminozide tolerances. The suit is based on existing Massachusetts and federal laws. The state law requires that tolerances adopted within the state conform to tolerances set by the federal government under the Federal Food, Drug, and Cosmetic Act. The suit also contends that federal law prohibits states from preempting federal bodies in setting tolerances because such action would place an unconstitutional burden on interstate commerce.

Regarding the actions of other states, the New York Health Department has requested that the Departments of Environmental Conservation, Agriculture and Markets, and Commerce carefully consider the proposals put forth in Massachusetts. The Maine Departments of Health and Agriculture will hold rulemaking hearings in mid-June to discuss proposals to achieve non-detectable levels in all products by 1988. The following is their proposed time line for achieving this goal:

	Raw Apples	Heat Processed	Baby Food
October 1986	5 ppm	1 ppm	Non-detectable ND
October 1987	3 ppm	ND	ND
October 1988	ND	ND	ND

The New Jersey Health Department has recommended that their Department of Environmental Protection regulate daminozide as a Restricted Use pesticide. The Connecticut Health Department is unable to characterize the risk associated with dietary exposure of daminozide and will reassess their position when more exposure data become available.

The impacts of a lower state tolerance and attendant publicity would be to require food producers and processors to:

a. Establish new elaborate monitoring, testing, and recordkeeping procedures to ensure that residues in foods entering the distribution area serving the state do not exceed the state tolerance. (Most fresh and processed foods are distributed to several states from a single regional distribution center. Thus, a tolerance set by one state will affect shipment of products to other states.);

b. Physically segregate lots or batches of already produced foods containing residues in excess of the state tolerance, marking or flagging them, and otherwise physically ensuring that such products are not shipped into the regional distribution system serving the state;

c. Physically remove lots or batches of already produced foods containing residues in excess of the state tolerance from grocery store shelves within the state and the distribution system serving the state. (Typical shelflife for processed foods is up to three years. Therefore, back records will have to be reassessed for compliance.);

d. Suffer impairment of brand or product image which would lead to loss of sales; and

e. Avoid future use of the pesticide to assure that lower state tolerances are achieved, thereby sacrificing the benefits of the pesticide and causing crop yields to decrease and/or product quality to deteriorate.

The net effect of these impacts is to disrupt interstate commerce and artificially to increase food production and distribution costs, ultimately forcing inflation of consumer prices.

(2) To our knowledge, there has been no systematic study of the total costs imposed on grain products producers by differing state tolerances for EDB. It is clear,

however, that grain products producers have incurred substantial additional product testing, monitoring and distribution expenses to assure compliance with differing local EDB tolerances. Thomas P. Grumbly, an economics expert and former USDA official, testified and introduced an economic study in litigation challenging the Florida tolerance for EDB of 1 part per billion (ppb) in grain products. He showed that grain products move extensively in interstate commerce, that differing state EDB tolerances would force substantial alterations in the food transportation network and that enforcement of the Florida tolerance would cost the food industry between 25 and 50 million dollars a year. Similar costs and dislocations would be caused by differing EDB standards in other states. Because all EDB grain uses were cancelled by EPA, EDB residues in grain products were progressively reduced, and eventually eliminated, and the adverse effects of differing state tolerances were correspondingly diminished over time.

(3) EDB and daminozide are the only food use chemicals we know of that are currently subject to state residue limits different from EPA tolerances. However, EPA has under review a number of important food use chemicals for which safety questions may be raised and new studies required. These include Alachlor, Captan, Linuron, Ethylene Oxide, Inorganic Arsenicals (Calcium Arsenate) and Captafol. It is important that the states not be permitted to issue differing tolerances for these and other chemicals. EPA is the only regulatory body with the necessary resources, expertise and national perspective to set reasonable and uniform pesticide tolerance levels.

If I or anyone at NFPA can be of further assistance to the committee, please do not hesitate to contact me.

Yours truly,

LAWRENCE T. GRAHAM.

Enclosure.

[Appendix A]

PROPOSED FINAL REGULATIONS

105 CMR 515.000: DEPARTMENT OF PUBLIC HEALTH

105 CMR is hereby amended by making the following amendments to Chapter 515:

(1) In section 515.003, after the definition of "Fish", insert:

Heat-Processed as applied to food, means food for human consumption which has been treated by heat to raise the temperature of the food to 145° Fahrenheit or greater.

(2) Insert a new section, 515.008 as follows:

515.008: Action Levels for Daminozide

(1) The action level for daminozide in infant or baby food is:

Effective October 1, 1986, 1 part per million;

Effective October 1, 1987, any detectable amount by a gas chromatography/mass spectrometry (GS/MS) method with a sensitivity of 0.01 parts per million or by other comparable analytical methods approved by the Commissioner of Public Health.

(2) The action level for daminozide in heat-processed apple sauce and juice products is:

Effective October 1, 1986, 5 parts per million;

Effective October 1, 1987, 1 part per million;

Effective October 1, 1988, any detectable amount by a gas chromatography/mass spectrometry (GS/MS) method with a sensitivity of 0.01 parts per million or by other comparable analytical methods approved by the Commissioner of Public Health.

(3) On or before July 1, 1987, the Director of the Division of Food and Drugs shall cause to be conducted a public hearing pursuant to M.G.L. c.30A, § 2 to consider whether or not, based upon the information then available, the October 1, 1987 and October 1, 1988 action levels specified in subsections 515.008 (1) and (2) are technologically feasible.

REGULATORY AUTHORITY

105 CMR 515.000: M.G.L. c.94, §§ 186 and 192; M.G.L. c.111, §§ 5 and 6.

The CHAIRMAN. Well, Mr. Ely, I think you kept him inside the law. Glad to have you here this morning at this table. Bolusky, is it? Did I pronounce that right?

Mr. BOLUSKY. Bolusky.

The CHAIRMAN. Good.

STATEMENT OF BENJAMIN C. BOLUSKY, DIRECTOR OF GOVERNMENT AFFAIRS, AMERICAN ASSOCIATION OF NURSERYMEN, INC., ACCOMPANIED BY DR. DAVID HAMILTON

Mr. BOLUSKY. Thank you, Mr. Chairman. It is with great pleasure that the American Association of Nurserymen welcomes this opportunity to comment on the proposed amendments to FIFRA.[10]

Accompanying me today on my left is our director of technical and landscape services, Dr. David Hamilton.

The American Association of Nurserymen is the national trade organization of the nursery, landscape, and garden center industries.

AAN represents more than 3,500 firms engaged in all aspects of the nursery industry, including the grower, wholesale, and retail segments.

Our members are overwhelmingly small businesses who depend upon the availability of safe pesticides. We wholeheartedly support FIFRA's role in ensuring only safe pesticides reach the marketplace, and in delineating the safe use of these pesticides.

Pesticides reach the nursery marketplace in a number of ways, but perhaps the most important manner is via the interregional project No. 4 which conducts the research necessary to make pesticides registered for other uses more promptly available to the nursery industry.

Regrettably, the administration's fiscal year 1987 budget proposes to zero out the IR-4 program. While AAN is vigorously opposing its elimination, IR-4's future is uncertain at this given time. So while debating legislation to amend FIFRA, we implore this committee to bear in mind the consequences of greatly diminished availability of pesticides to the nursery industry, should the administration succeed in dismantling IR-4.

For many comparatively small scale or specialty pesticide uses, such as the nursery industry, there is often insufficient economic incentive to entice pesticide manufacturers to develop the data needed to register these uses.

Nursery production has never been considered a sufficiently large pesticide market to warrant all of the necessary research and registration costs to develop new pesticides.

It has always been more economically feasible for manufacturers to develop pesticides for so-called major markets such as corn, wheat, or soybeans, if for no other reason than an acre of corn, for example, contains only corn.

By comparison, a nursery acre may contain up to 25 different varieties of growing plants requiring many different pesticides within that very single acre. It is important that this committee fully appreciate the susceptibility of the nursery industry to the loss or removal of approved minor use pesticides by either chemical manufacturers or EPA.

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[10] See p. 230 for the prepared statement of Mr. Bolusky.

Congress must also recognize that development of new pesticides and access to already registered pesticides for ultimate use by the nursery and other minor use industries will depend, to a great extent, upon the difficulty registrants have in introducing new pesticides or in adding new uses to existing labels.

AAN urges Congress to grant a reregistration fee exemption for pesticides used on agricultural nonfood or feed minor use crops, especially those pesticides that come under the IR-4 program.

FIFRA granted pesticide regulatory authority to the States, not to local jurisdictions. However, local jurisdictions are enacting restrictions and regulating the use of pesticides, even when such pesticides have already undergone all of the necessary extensive registration tests and have been certified for safe use by State and Federal governments.

AAN thus respectfully urges Congress to reaffirm its original intent to preempt local jurisdictions from regulating the use of pesticides. With respect to training, certification, and right-to-know issues, at the present time, negotiations with EPA are continuing in an effort to develop farmworker protection standards for agricultural workers who handle or may be exposed to pesticides.

It is imperative that any FIFRA amendments be compatible with the EPA farmworker protection standards; otherwise, confusion and chaos will likely reign throughout the agricultural community, in trying to address perhaps several different sets of regulations.

In general, Mr. Chairman, we support S. 2346, introduced by you, most recently, as we believe this legislation more closely reflects the important concerns of minor use pesticides and their impacts upon the nursery and minor use industries.

In conclusion, Mr. Chairman, the American Association of Nurserymen is committed to seeing FIFRA amendments passed this year. We are prepared and willing to cooperate fully to ensure such does come to fruition, yet we wish to remind the Congress, that the nursery industry is dependent upon the availability of affordable and safe minor use pesticides.

Congress must consider careully all of the broad impacts any FIFRA amendments will have upon the viability of small businesses, such as nurserymen, who compose the majority of the minor use markets in this country.

Time and again, Mr. Chairman, you have afforded the American Association of Nurserymen the opportunity to testify on behalf of the nursery industry and we would like to, once again, thank you.

The CHAIRMAN. Thank you, Mr. Bolusky, for a fine statement Mr. Hutt.

STATEMENT OF PETER HUTT, REPRESENTING THE GROCERY MANUFACTURERS OF AMERICA

Mr. HUTT. Mr. Chairman, I am Peter Barton Hutt, partner in the law firm of Covington & Burling. During 1971 to 1975 I served as chief counsel for the U.S. Food and Drug Administration, and I am appearing today on behalf of the Grocery Manufacturers of America.[11]

GMA is a 75-year-old national trade association comprised of over 130 companies which manufacture food and other products sold in retail grocery stores throughout the United States.

GMA members employ over 2.5 million people nationwide and have annual sales in excess of $250 billion.

My testimony today addresses only the critical need for legislation to assure national uniformity in the regulation of the levels of pesticide residues found in or on food.

This is a matter of great importance to agricultural producers, food processors, and the public at large.

Legislation to achieve national uniformity in this area is needed because virtually every State has one or more laws regulating the levels of pesticide residues in or on food, and repeated attempts to obtain national uniformity in the enforcement of these laws have been unsuccessful.

Pesticides are of critical importance to food production in this country and our nationwide food production and marketing system depends upon uniformity in their regulation.

Today, our food production, processing, and distribution constitutes a truly national undertaking. A given raw agricultural commodity may be grown in one State, stored for a period of time in another, partially processed in a third, made into a finished product in a fourth, sent to a distribution warehouse in a fifth, and from there sold to consumers in retail stores throughout the country.

Most of our agricultural produce is shipped to more than 21,000 domestic food processors where it is prepared for the retail food market.

In 1980, these companies processed and sold more than 338 billion packages of food, valued at $245 billion.

These hundreds of billions of individual food items have one element in common. Their safety is evaluated, regulated, and closely monitored by two Federal agencies, EPA and FDA.

For manufacturers to supply safe food at reasonable prices to consumers throughout the country, these Federal agencies must be able to establish and enforce a single safety standard for levels of pesticide residues in or on food.

Within the past 3 years, two specific situations have arisen that illustrate the chaos, confusion, and most of all, economic waste that occurs when States impose restrictions on the levels of pesticide residues in or on food different from those imposed by EPA and FDA. The first involved ethylene dibromide, EDB, and the second involves daminozide.

For many years, EPA had registered EDB for use on certain food crops. When new information became known about its potential toxicity, EPA began a systematic review of that information, leading ultimately to an orderly withdrawal of the pesticide from the market.

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[11] See p. 235 for the prepared statement of Mr. Hutt.

In December 1983, in the middle of this orderly EPA process, the State of Florida took unilateral action to ban any food product found to contain any detectable amount of EDB.

About 2 months later, EPA and FDA imposed new limitations on the permissible levels of residues of EDB in food, that provided a wide margin of safety for the public.

Notwithstanding this action by the responsible Federal agencies, a number of States refused to accept the Federal limitations and instead imposed their own.

Today, there remain four different requirements for levels of EDB residues in or on food: The Federal requirements, requirements set by Massachusetts and Maine, requirements set by New York and New Jersey, and requirements set by California. There are in addition more than those, but those are the only ones we have specific information on today. More recently, the same problem has arisen with yet another pesticide, daminozide. The EPA Scientific Advisory Panel concluded in September 1985, that the available data do not demonstrate that daminozide is a carcinogen.

Based upon that scientific evaluation by recognized independent academic experts, EPA reduced the permissible residue level of daminozide in food and undertook additional steps to obtain sufficient information to determine what additional action is warranted to protect the public health.

In spite of this responsible Federal action designed to provide ample public health protection, the State of Massachusetts has recently proposed three alternative actions to establish permissible levels of daminozide within Massachusetts.

Two of those alternatives would differ substantially from the Federal action. And not to be outdone, we have just been informed that Maine is considering yet another approach that would differ both from Massachusetts and from EPA.

The EDB and daminozide episodes cannot be viewed as aberations that are unlikely to be repeated. EPA is reviewing approximately 300 pesticides currently used on food crops and the thousands of tolerances related to those uses. New pesticides are continually being approved by EPA for food use. As decisions are reached by EPA and FDA on these matters, there should be assurance that conflicting decisions by the States will not cause major disruptions in food production and marketing.

GMA therefore strongly urges adoption of legislation that will assure national uniformity in the regulation of levels of pesticide residues in or on food. Such legislation should incorporate the following principles, which will provide stability in agricultural production and marketing, a high standard of public health protection, and a clear role for States to protect the interests of their own citizens.

First, legislation should establish the general rule that Federal requirements relating to the levels of pesticide residues in or on food will constitute the national standard.

Any State standard should be required to be identical, with certain exceptions noted below.

Second, any State should have concurrent jurisdiction to enforce the levels of pesticide residues that are established under Federal law.

Third, any State official should be authorized to request a Federal agency to change the Federal requirements to reflect new information. The Federal agency should be required to give a prompt response.

Fourth, any State should be permitted to request an exemption in order to impose a limitation lower than the Federal level, upon a showing of compelling and unique local conditions, or a lack of Federal interest, where the matter is primarily local in nature and local interests must be protected.

Fifth, the Federal agencies should be required to establish an advisory committee comprised of State officials engaged in the regulation of the levels of pesticide residues in or on food, in order to receive sound advice on State issues.

Sixth, petitions from State officials should be acted upon only by the highest Federal official responsible for the matter involved, and should not be delegated to lower officials.

Seventh, whenever a State determines, on the basis of an adequate record, that a pesticide residue represents an imminent hazard to the citizens of its jurisdiction and that immediate action is necessary to prevent that imminent hazard, it should be free to do so as long as there is a prompt petition requesting Federal action.

Such legislation would provide an appropriate role for State governments in regulating pesticide residues in or on food, while at the same time balancing Federal and State interests.

The Association of Food and Drug Officials representing many of the State officials responsible for enforcing food safety requirements have recently informed GMA that they support this approach.

Thank you, Mr. Chairman.

[Questions submitted by Senator Wilson to the Grocery Manufacturers of America and answers thereto:]

Question 1. Each of your statements expresses support for including a provision to assure national uniformity of tolerance levels in pesticides due to the problems resulting from inconsistent standards. By way of example, you mention EDB and daminozide. While the Committee is familiar with events surrounding EDB, it would appreciate receiving more specific data on the uses of daminozide, existing federal tolerances, the proposals being considered by Massachusetts, Maine and any other state that would result in a different standard, and the impact that such a state standard would have upon your members.

Answer 1. Daminozide is a plant growth regulator used to reduce vegetative growth, promote flower bud initiation, increase crop yeld, control time of crop maturation, prevent preharvest fruit drop and in general improve market quality of crops at harvest and/or after storage. It is a systemic pesticide used primarily on apples, peanuts, sour cherries and concord grapes, and has no readily available substitute. The substance is manufactured by Uniroyal Chemical Company under the trade names of Alar-85 (for use on fruit crops) and Kaylar-85 (for use on peanuts).

In July, 1984 EPA initiated a special review of daminozide, and in September, 1985 announced its intention to cancel the substance. A copy of EPA's draft report on daminozide was forwarded to the Scientific Advisory Panel (SAP) for review as required under FIFRA and was rejected on the basis that "the data available are inadequate to perform a qualitative risk assessment".[12] Levels of public exposure are reported by EPA were inaccurate and were revised based on information provided to the SAP on actual use patterns and levels.

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[12] October 4, 1985 FIFRA Scientific Advisory Panel "Review of a Set of Scientific Issues Being Considered by EPA in Connection with the Special Review of Daminozide". Attachment 1.

EPA reviewed exposure estimates and determined that actual exposure to daminozide is only 10-15% of the amounts estimated in early reports. On January 22, 1986 EPA issued interim regulatory measures for the continued use of daminozide, which included action steps to reduce public exposure and to generate a more complete data base to evaluate risk of the subtance.

Exposure reduction measures include labeling changes to reflect lower allowed application rates and a separately labeled product for use on concord grapes. An interim tolerance for residues in apples of 20ppm (down from 30ppm) was proposed by the Agency on April 16, 1986 and should be finalized soon.

Studies are currently being conducted by Uniroyal and include toxicology testing, metabolism studies, analytical methodology development, degradation studies, feeding studies, residue field trials and a marketbasket survey to collect information on residue level in fresh fruits and manufactured food products. EPA will review these studies and is slated to make a final determination on the safety of daminozide by Spring, 1988.

Some state health officials have raised concern over the ingestion of daminozide-treated products by infants and young children. In particular, the Massachusetts Public Health Council, on May 13, 1986, issued final regulations on daminozide. Included in the regulations are action levels of 1ppm for infant and baby foods and 5ppm for heat-processed apple products and juice products; these action levels are effective October 1, 1986. A time-phased approach to implement even lower tolerances is provided in the regulations, with an October 1, 1988 date for all products to comply with a non-detectable residue allowance. The State of Maine has also indicated that it may take some similar form of action, and a bill has been introduced in the New York Assembly that would prohibit the sale, use, possession or transportation of daminozide within the state.

State health officials from other states, as well as the Association of State and Territorial Health Officials, have indicated their willingness to support the EPA decision and do not agree with the actions taken by the Massachusetts Public Health Council. Dr. Peter Galbraith, Chief of the Bureau of Health Promotion for the State of Connecticut, presented that State's position in a letter to Dr. Bailus Walker of the Maine Department of Health. The letter, dated March 6, 1986, noted that "since we are unable at this time to characterize the levels of risk associated with dietary exposure to daminozide and UDMH, it is premature to implement action levels or tolerances that vary from those being proposed by EPA."[13]

The economic impact on the grocery industry of different state standards for daminozide and other pesticide residues is difficult to assess and will be discussed in further detail in the response to the second question. The impact on the apple growing industry is well documented and according to EPA cancellation of daminozide would result in a 15% economic loss to growers in the 1st year.

Question 2. Similarly, given that four different tolerance standards for EDB have existed for nearly two years, what has been the practical impact upon the businesses of your members? Does the situation impose additional costs upon your industries or their consumers and, if so, can you quantify them? Are there safety concerns which arise from differing state standards?

Answer 2. There has not been a complete assessment of the impact of different EDB standards on the food industry, in part because quantification of the various factors is difficult given the dynamics of the market. Such an assessment cannot be measured in loss of product alone. Many factors must be considered including the cost of product recalls, loss of commodity sales, redistribution costs for products that cannot be sold in a particular market, damage to brandname reputation, loss of marketshare for products, as well as costs for tracking distribution, tracing commodity sources, monitoring regulatory activity in 50 states instead of being able to rely on one federal standard and ultimately the loss of public confidence in the food supply.

The American food supply is deemed the safest and most economical in the world and the U.S. food industry is committed to maintaining this standing. The use of a variety of standards for pesticide residues, however, interferes with a manufacturer's ability to efficiently supply a wholesome and reasonably priced product; the accompanying need for relabeling products, reformulating products, tracing commodity sources and tracking distribution increases costs for every standard different than the federal standard, and those costs are eventually passed on to the consumer.

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[13] March 6, 1986 Letter from Dr. Peter Galbraith, Chief, Bureau of Health Promotion, State of Connecticut, to Dr. Bailus Walker, Commissioner, Maine Department of Health. Attachment 2.

Often, the benefit of lower standards proposed by states will not provide any greater safety margin, but will increase consumer cost. As an example, independent EDB actions by states did not provide any real gain in safety, but increased the consumer cost for grain products without any of the claimed health benefits. Each manufacturer, in order to ensure the legality of their product in states having different standards was required to monitor for each of the four different standards. There was no significant health benefit from the Massachusetts tolerance of 1ppb as opposed to the EPA tolerance of 30ppb, yet the food industry and the consuming public were required to pay for the difference.

Less than 7% of the nation's food products from grain were estimated to be above the national tolerances for EDB residues, but the loss in confidence in the food supply caused sales to drop over 20% (as reported by GMA member companies). With a national market for flour, baked goods and prepared mixes in excess of $2 billion annually, that amounted to a wastage of approximately $30 million each month.

Allowing states to set pesticide residue tolerances different from those established by EPA will eventually undermine public confidence in Federal regulatory authority. Confusing the public with a multitude of standards is not in the best interest of the consumer, the retailer, the processor, or the farmer; no one gains through these actions.

That the public consciousness is negatively impacted by such activity, most apparent in the mass hysteria during the EDB crisis and to a lesser degree in the daminozide situation, is documented in a paper prepared for EPA by Harold Sharlin, HIS Associates. In his paper entitled "EDB: A Case Study in the Communication of Health Risk"[14] Mr. Sharlin identifies the problems EPA encountered in communicating the health risk, and the role of the media in exacerbating that problem. It has never been disputed, however, that the cause of the EDB crisis was an independent action by a state regulatory body.

In the aftermath of the EDB crisis state health officials commented that "uniformity of standards is a top priority" and that it is necessary for state agencies to "maintain a credible working relationship with EPA, and with responsible industry representatives".[15]

Question 3. Beside EDB and daminozide, are you aware of any other food use chemicals which have more stringent state standards than existing federal tolerances? If so, would you please provide the Committee with a list of these chemicals, their uses, and the different federal and state tolerance levels? To ask the question differently, if Congress were to enact a pesticide uniformity provision, what specific food use chemicals, in addition to EDB and daminozide, and which states would be immediately affected?

Answer 3. Currently, GMA is unaware of any food use chemicals, other than EDB and daminozide, which have state standards more stringent than the Federal standards. One must, however, look toward the future. As EPA continues to review pesticide products in its Special Review program and publish those results, the likelihood of states taking independent action—as in the case of Massachusetts and daminozide—is increased. The fact that the review process for a number of important pesticide products is proceeding to publication further underscores the need to ensure EPA authority.

The enactment of national uniformity legislation at this time will allow EPA to continue to work through its Special Review program without having to put out more brushfires like EDB and daminozide, with their accompanying costs. Interaction between state and federal regulatory authorities must, however, be encouraged and should be provided for in the national uniformity provisions.

[Attachment 1]

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA) SCIENTIFIC ADVISORY PANEL

Review of a Set of Scientific Issues Being Considered by EPA in Connection With the Special Review of Daminozide

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) has completed review of a set of scientific issues associated with daminozide. The review was conducted in an open meeting held in Arlington, Virginia, on September 26, 1985. All Panel members were present. In addition, two new designees to the SAP, Dr. Thomas Clarkson and Dr. James Swenberg, participated in the review.

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[14] "EDB: A Case Study in the Communication of Health Risk" dated December 5, 1984. Submitted to the Office of Policy Analysis, Environmental Protection Agency by Harold Sharlin, HIS Associates, Washington, D.C.

[15] ASTHO Press Release on EDB, 3/19/84. Attachment 3.

Public notice of the meeting was published in the Federal Register on Friday, August 30, 1985.

Written and oral statements were received from Uniroyal Company and the National Food Processors Association. Written statements alone were received from the New Jersey State Horticultural Society and the New Jersey Apple Institute; Northwest Horticultural Council, Yakima, Washington; and the International Apple Institute. Oral statements alone were received from a number of apple growers.

In consideration of all matters brought out during the meeting and careful review of the documents presented, the Panel unanimously submits the following report:

REPORT OF SAP RECOMMENDATIONS

The Scientific Advisory Panel (SAP) has reviewed the materials presented to it on daminozide, and responds as follows to the issues presented to it by the Agency:

Issue 1. Several studies indicate that daminozide is oncogenic in laboratory animals. Does the Panel agree with the Agency's qualitative assessment (i.e. weight of the evidence conclusions) of the oncogenic potential of daminozide?

Response.—The data available are inadequate to perform a qualitative risk assessment. The Toth Alar studies do give rise to concern over the potential oncogenicity of daminozide. The Panel feels that the other studies are equivocal. None of the present studies are considered suitable for quantitative risk assessment. Given the fact that the Toth data have been available for eight years, the Panel does not understand why EPA has neither requested, nor the registrant initiated in a more timely fashion, additional oncogenicity testing. Quantitative risk assessments cannot be appropriately carried out until adequate data become available.

Issue 2. Studies indicate that UDMH, a metabolite of daminozide, is oncogenic in laboratory animals. Does the Panel agree with the Agency's qualitative assessment (i.e., weight of the evidence conclusions) of the oncogenic potential of UDMH?

Response.—The recent inhalation studies provide some evidence of potential oncogenicity. However, these studies also present a number of discrepancies which require further clarification. While the inhalation studies appear to be appropriate for assessing risk to applicators, their use in assessing dietary risk is questionable.

Issue 3. Do you agree with the approach the Agency has used in estimating UDMH residue level in fresh and processed foods?

Response.—The Panel does not believe that the residue levels employed by the Agency, particularly those for meat, milk and eggs, are reflective of actual residue that can be expected to occur.

Issue 4. Has the Agency estimated the risk associated with the use of daminozide (including the risk associated with UDMH in both raw and processed food) in a competent and technically sound manner?

Response.—The Panel wishes to refer the Agency to the issues it has raised in questions one, two and three. The Panel does have reservations over the technical soundness of the Agency's quantitative risk assessments as regards daminozide and UDMH in both raw and processed food.

For the Chairman.—Certified as an accurate report of Findings:

PHILIP H. GRAY, Jr.,
Executive Secretary, FIFRA Scientific Advisory Panel.

Date: October 4, 1985.

[Attachment 2]

STATE OF CONNECTICUT,
DEPARTMENT OF HEALTH SERVICES,
BUREAU OF HEALTH PROMOTION,
Hartford, CT, March 6, 1986.

BAILUS WALKER, Jr., Ph.D., M.P.H.,
Commissioner, Department of Public Health, the Commonwealth of Massachusetts, 150 Tremont Street, Boston, MA.

DEAR DR. WALKER: Thank you for requesting comments on your proposal for handling daminozide in foods. The attached position paper represents our current thinking, and we believe it is consistent with a national approach being endorsed by ASTHO and others.

Our position provides an opportunity for reassessment when better exposure data become available.

Your proposed action for testing and establishment of action levels refers to daminozide. My understanding is that UDMH is a critical factor in driving the EPA efforts to cancel. We would be interested to know how you plan to collect a statistically valid sample which would characterize the daminozide as well as the UDMH exposure. Are you proposing to set an action level for daminozide exclusively, or do you have plans for UDMH?

We look forward to working with you and hope that we can maintain a consistent regional and national response.

Sincerely,

PETER D. GALBRAITH, D.M.D., M.P.H.,
Chief, Bureau of Health Promotion.

Enclosure.

DAMINOZIDE/ALAR—MARCH 6, 1986

1. The U.S. Environmental Protection Agency announced in January a number of interim regulatory measures that have been imposed as a condition for the continued use of the pesticide daminozide.

Daminozide is a plant growth regulator used primarily on apples intended for the fresh produce market (38% of the US fresh market apples).

EPA has had a tolerance of 30 ppm for daminozide and is proposing to reduce that tolerance to 20 ppm. In addition to this, the following is underway:

a. Uniroyal, the only manufacturer of Alar has agreed to include an advisory in every bag of Alar cautioning against the use of daminozide on apples intended for apple sauce.

b. The manufacturers of baby foods have voluntarily agreed to limit the use of daminozide treated commodities in baby foods.

c. Due to continued concerns about the potential risk of cancer from lifetime exposure that triggered the earlier announcement of intent to propose cancelling all food uses of daminozide, EPA has called for additional data in order to fully assess potential risks so that a final decision can be made.

d. Farmers will be told to reduce the usage of daminozide in the spring from 8 to 4 pounds per acre and mid-season application should be reduced from 4 pounds to 3 pounds per acre.

e. Current exposure estimates by EPA are 10-15% of the levels originally projected. Original estimates had been based on maximum exposure levels.

f. A national market basket survey will be done to determine the level of daminozide and UDMH residues in fresh apples, apple juice and apple sauce in both baby and adult food, cherry filling, peanuts, peanut butter and concord grape juice. Preliminary results will be available in the summer of 1986 and final results in the spring of 1987.

2. The Northeast Center for Environmental Public Health went through a reasonable process involving EPA, industry and the manufacturer resulting in a position that had wide support not only within the Center but within the Association of State and Territorial Health Officials.

3. Since we are unable at this time to characterize the levels of risk associated with dietary exposure to daminozide and UDMH, it is premature to implement action levels or tolerances that vary from those being proposed by EPA. Testing by individual states would not, at this time, provide any valuable information particularly without consensus on the sampling and analytical techniques.

4. EPA is implementing a process to assess inter-laboratory variability and consistency as it relates to the analysis of daminozide and UDMH. The outcome should be a recommendation endorsing either the EPA GC Electron Capture Method or the Procter and Gamble Conditt Method (GCMS). It is possible that both methods will be endorsed. Until this process of validating the analytical procedures is complete, meaningful action levels/tolerances cannot be set.

5. The EPA/industry national market basket survey will provide a statistically valid sample. Preliminary results will be available this summer and, at that time, it may be appropriate to reconsider tolerances.

6. The potential threat to public health is not acute, and therefore, an emergency response is not indicated.

[Attachment 3]

ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS,
McLean, VA, March 20, 1984.

FIVE NORTHEASTERN HEALTH DIRECTORS CALL FOR ZERO LEVELS OF EDB

Health directors of five northeastern states—Connecticut, New Jersey, New Hampshire, Rhode Island and Vermont—today reaffirmed their commitment to the complete elimination of EDB from the food system within two years, with a substantial reduction during the first year.

The five states form a sub-group within the Association of State and Territorial Health Officials which is attempting to achieve uniform national standards. To that end Dr. Douglas S. Lloyd, Connecticut Health Commissioner and President of ASTHO, has convened a national Task Force which will meet in Washington D.C. on March 26 and 27.

In announcing the position of the five northeastern states, Dr. Lloyd emphasized that, contrary to recurring reports, the states have not adopted new and more stringent standards. He said the five states support EPA guidelines, with the exception of those for infant food.

"There is no acceptable level of EDB in infant food," the ASTHO president declared.

Lloyd said that ASTHO has received a commitment from William Ruckelshaus, Administrator of the U.S. Environmental Protection Agency, and from industry representatives, to work together for an earlier phaseout of the carcinogen than the 3–5 year time frame for which EPA has called.

"It is important now, and for future similar situations," Dr. Lloyd said, "that we maintain a credible working relationship with EPA, and with responsible industry representatives."

"Uniformity of standards is a top priority" according to Dr. Richard Goldstein, New Jersey Commissioner. His state will host a regional meeting on April 11, following the receipt of a major report from the food processing industry expected on April 2nd.

"The public interest is not well served by an ongoing debate over acceptable levels of EDB," Dr. Lloyd said. "The job before us is to protect the public health by eliminating this chemical from food stuffs."

"That means," he continued, "working with industry to check raw grain as it comes into the food pipeline. Individual states taking boxes off grocery shelves, and analyzing them, is not enough. Nationwide enforcement is essential in this issue."

The states expected to send representatives to the ASTHO EDB Task Force meeting include California, Colorado, Connecticut, Florida, Illinois, Michigan, Minnesota, New Jersey, New York, Oregon, South Carolina, and Texas. Dr. Donald Lyman of California has agreed to serve as chairman of the Task Force.

In a prepared policy statement, the 5-state group said that, over the short term, there is no significant public health threat posed by the current levels of EDB. However, they stressed that complete elimination of EDB is the only acceptable final position.

The CHAIRMAN. Thank you, Mr. Hutt. Several of you have addressed what bothers me. I am on the horns of a dilemma. I am a great States rights man. How many are lawyers here at this table? Three. Is it constitutional to do what my friend just suggested?

Mr. HUTT. In our opinion, Mr. Chairman, there is no question that any reasonable judge would so hold.

The CHAIRMAN. Well, I certainly agree, you know, that you can get on the local level or the State level, you can get a lobbying effort rolling, and you can just absolutely contradict the Federal law.

It is an interesting question.

Mr. HUTT. Mr. Chairman, the courts have uniformly upheld the rights of the U.S. Congress to preempt local action in appropriate situations. The only question that has ever arisen occurs when the Federal Government does not make preemption clear, and the courts are then required to interpret whether there is implicit Federal preemption rather than explicit Federal preemption.

The **Chairman**. Well, let my ask my lawyer: Did we make it explicitly clear? Good morning. [Laughter.]

We are talking about the constitutionality and they say that there is no question about it. Now, what I want to know is, in our bill, are we very explicit?

Mr. **Franks**. We are.

The **Chairman**. All right. That may be worth what I charge for it, but——

[Laughter.]

The **Chairman**. A couple of questions. You all are very patient and I appreciate it, but, you know, I know nothing about this. A Senator is not supposed to acknowledge that he does not know everything, but this one certainly does not know everything. Some days I wonder if I know anything, compared to what I hear on the Senate floor.

But this is such a profoundly important piece of legislation, and it bothers me, that so little attention is given to it, and there is almost no public discussion, let alone understanding of what the problems are of the industry.

Of course it is fashionable to beat up on corporations and businesses, but the consumer has got a big stake in all of this, an enormous stake in terms of what they pay, the quality of the things they buy, and so forth.

Well, let's get back to the conditional registrations. I have been told a number of times, that conditional registrations were obtained too easily in the past, and without submission of adequate health and safety data.

In your opinion, should the authority for conditional registration be retained? I think I know the answer. Anybody want to comment? Don't everyone speak at once. I notice a lawyer is going to answer this one.

Mr. **Ely**. I will be glad to comment on that.

The **Chairman**. All right.

Mr. **Ely**. In our opinion, the authority should be retained. The bill, S. 2215, would retain conditional registration authority but significantly restrict it. Our concern is that that significant restriction does not give EPA discretion in the case of minor-use pesticides, where it is appropriate, to waive certain data requirements where there would be limited exposure, and limited economic incentive for the pesticide producer to do a lot of studies.

So we think it should be retained, and we think there should be some discretion at EPA to take into account minor use patterns.

The **Chairman**. Anybody else?

[No response.]

The **Chairman**. Will the registration of old pesticides and the proposed reregistration fee result in higher pesticide costs for farmers and processors?

Mr. **Keeney**. It definitely will; there is no doubt about that. The question is whether this can be passed on to consumers, or not, and we believe that it cannot be passed on to consumers, and that the agricultural producers will have to absorb the difference in cost. So this is a real concern of ours; this whole area.

The **Chairman**. Your point being that the farmer will pass it on?

Mr. **Keeney**. Generally they cannot. For example, automobile manufacturers certainly can pass on added costs. For the most part farmers cannot.

The **Chairman**. Any other comments?

Mr. **Graham**. I agree.

The **Chairman**. You agree.

Mr. **Graham**. Yes, sir.

The **Chairman**. Very well. Thank you very much, gentlemen. I hear, and I have often said myself, that you cannot tax the corporation, and I believe that, because a corporation is just a tax collector. It is a little bit too general to say the consumer pays in the long run, because in the instance of agriculture, as it is now operated, with so much Government intervention, the farmer cannot pass it along, in so many cases.

A right interesting byproduct of the tragedy at Kiev is that it is already affecting the wheat futures substantially. It is going to be interesting to see how that thing comes out.

Thank you very much for your excellent testimony. We appreciate your helping us in getting a better perspective on it.

Senator **McConnell**. Mr. Chairman, I would like to put my two-page statement in the record.[16]

The **Chairman**. Without objection, sir.

Next, we have Mr. William J. Walsh, third senior staff officer of the Commission on Life Sciences, National Research Council, National Academy of Sciences, Washington, DC.

You may proceed, sir.

STATEMENT OF WILLIAM J. WALSH III, SENIOR STAFF OFFICER, COMMISSION ON LIFE SCIENCES, NATIONAL RESEARCH COUNCIL, NATIONAL ACADEMY OF SCIENCES

Mr. **Walsh**. Good morning, Mr. Chairman, and distinguished members of the committee. I first have to apologize for my voice. As the pollen count went up it kept going down.

The **Chairman**. I have the same problem.

Mr. **Walsh**. I am Bill Walsh, currently serving an IPA tour on the National Research Council.[17] Prior to joining the staff of the NRC last November, I spent 10 years as coordinator for Biomedical Research and Health Affairs in the Department of State's science bureau.

This statement is my own and made in response to your request, Mr. Chairman. It does not necessarily represent the views of the organizations with which I am or have been affiliated, nor is it made on their behalf.

My statement focuses on the relationship of FIFRA to the important field of biotechnology, which promises to be a $100 billion industry by the year 2000.

FIFRA is, as we all know, a cost-benefit statute. As the regulatory agency responsible for its administration, EPA is obliged to weigh the costs and benefits of the actions it takes to carry out its responsibilities under FIFRA.

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[16] See p. 187 for the prepared statement of Senator McConnell.

[17] See p. 250 for the prepared statement of Mr. Walsh.

The problem is—the problem that I would like to bring before you—in regard to biotechnology, is that EPA has been looking at possible costs and benefits instead of scientifically based probable costs and scientifically probable benefits.

The purpose of my statement this morning, Mr. Chairman, is to propose that as you consider the reauthorization of FIFRA, you consider writing into the statute that costs and benefits be determined on the basis of scientifically determined probability and not on the basis of possibilities.

The reason for my recommendation is that important regulatory determinations that are adversely affecting the advancement of biotechnology—and its effects on medicine and agriculture and pharmaceuticals—are being made on the basis of perceived or imagined possible risks, in lieu of a realistic scientific assessment of probable risk.

I submit that regulation based on some nonscientist's perceived or imagined possible risks is bad regulation. But that is exactly what is happening.

It is costing the United States its leadership in biotechnology. It is costing farmers a tremendous amount. Experiments have been banned on potatoes, on corn, tobacco, strawberries, beans, and they are all being held up by this bad regulatory process.

And there is reason to believe that it is driving biotechnology research and experimentation both underground and to foreign shores. To demonstrate what I am talking about, I would like to trace EPA's application of a provision of FIFRA to biotechnology and show what the consequences of that application are.

Prior to the nonscientific ravings that the deliberate release of a genetically engineered micro-organism into the environment could possibly cause a catastrophe, the EPA permitted "small-scale field testing" of pesticides on up to 10 acres of land, or 1 acre of water.

But then on October 17, 1984, EPA published in the Federal Register a notice that states that EPA would determine whether "experimental use permits" would be required for all small-scale field tests involving micro-organisms—that is, biotechnology—which have been genetically altered or manipulated by humans.

In its justification for this restrictive action which discriminates against the biotechnology industry, EPA stated, "Microbial pesticides may replicate and spread beyond the site of application. They may not be subject to natural control. They could exhibit increased competitiveness. They may be difficult to control or eradicate after being introduced. And finally, that they may be unstable or transfusable to other micro-organisms."

Notice that the subjunctive mood and the words "may" and "could" are used throughout to express possibilities. There is not a single mention of a scientifically based probability occurring. Moreover, in the last sentence of EPA's justification for this restrictive action against testing of genetically engineered microbes, the EPA states that it does not have any reason to believe that any of the aforementioned possibilities will occur.

In their own words, EPA had no reason to believe that any of the possibilities they based their justification on would occur but they brought whole areas of research and experimentation in biotechnology to a screeching halt anyway.

I am reminded of a statement made at a seminar at the Brookings Institution in January 1985 by the former Director of NIH, Dr. Donald Fredrickson.

Dr. Fredrickson said that regulators must have the courage of their scientific convictions.

The Federal Register notice requires that researchers supply substantial amounts of data before EPA decides whether to permit small-scale field testing.

The data-collection effort can be prohibitively expensive and time consuming. The interim policy on small-scale field testing that was issued on October 17, 1984, is still in effect pending the imminent publication, I am told, of a final policy in the Federal Register.

It is my hope, and I think it is shared by many scientists, that the final policy regarding biotechnology will reflect costs, risks, and benefits based on scientific probabilities. If it is, I am confident that virtually all of biotechnology's organisms will be able to be small-scale field tested, without research stifling regulatory procedures.

So the two major points, Mr. Chairman, that I am trying to make are one, that cost benefit ought to be determined by scientific probabilities of scientifically based cost and benefit analyses, and second, that the biotechnology industry should not be discriminated against. That is, that researchers in the field of biotechnology should be permitted to carry out the same small-scale field tests that others can carry out cautiously and with scientifically based prudence.

I will omit the last whole section of my testimony because I see my time is up.

The CHAIRMAN. Your entire statement will be included in the record. You have really peaked my interest in this. Senator Leahy.

Senator LEAHY. Hello, Mr. Chairman. I have been attending a meeting of the Judiciary Committee, with Senator Denton. I knew this hearing was in your able hands here and there would not be much I could add at this time. I will ask to just put a statement in the record, if I may.[18]

The CHAIRMAN. That will be fine.

I was just going to ask Mr. Walsh, who is the last witness scheduled this morning—you had excellent testimony—I am one of these curious guys who wonder what footnotes mean, and you have footnoted your statement very well, and I am curious about page 5. You stated in your testimony that data-collection efforts are often prohibitively expensive and time consuming.

Then you refer, in the footnote No. 4, to EPA's March 21 letter to Professors Lindow and Panapoulos, and the comments of Drs. Martin and Johnson.

I have got to ask you what was in the letter. Would you mind telling me?

Mr. WALSH. Yes. Mr. Chairman, I have brought most of the references that I made in the footnotes, and this was a particularly disturbing thing. Professors Lindow and Panapoulos—you know—there is $3 billion in frost damage in the United States alone, and they came up before the Recombinant DNA Advisory Committee in 1982, and worked with the RAC—on which I sit as a nonvoting member—to try to get the RAC's best judgment and advice as to whether they could try to field test this ice mutant bacteria.

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[18] See p. 188 for the prepared statement of Senator Leahy.

In 1983, the Recombinant DNA Advisory Committee gave them permission. They said that they thought that it was a fine idea and they did not see anything wrong with it.

Then suit was brought by Jeremy Rifkin because NEPA had not—he claimed NEPA had not been looked at properly. Well, on January 21, 1985, Dr. Wyngaarden, the Director of NIH, issued a finding of no adverse environmental impact. But then, on March 21, 2 months later, as if the left hand did not know what the right hand of the Federal Government was doing, Drs. Lindow and Panapoulos received a letter from the Environmental Protection Agency—I think a 6-page letter—asking for huge amounts of data. These fellows are university professors. They had already supplied a considerable amount of data to the NIH.

Now, the same thing, in the meantime, was happening to Monsanto, but nobody feels sorry for Monsanto because everybody figures they have the money to collect the data, but some of the Monsanto people told me that they were reaching the bottom of their pockets, too, supplying all this data, before they could even field test on a small scale.

Steven Lindow sent me the 6-page EPA letter, and I sent it to two members of the Recombinant DNA Advisory Committee [RAC] for whom I have a great amount of respect to ask their opinions.

One is vice president for research, at Genentech, one of the prominent biotechnology firms. He sent a letter back to me in which he was pretty clear in saying: "If that is not bureaucracy at its zenith, I am not sure what is." I think he stated his case pretty well.

The **CHAIRMAN**. Yes. I would like the EPA letter to be made a part of the record. I assume this is public information.

Mr. **WALSH**. Yes; it is. It is not classified.

The **CHAIRMAN**. And also Dr. Martin's letter. Without objection, I am going to have this exchange of correspondence be made a part of the record.[19]

Now let's go back just 1 minute. I do not want to burden your voice because I have a little trouble with pollen, too, thus far; not as bad as yours. I think just for the record, you ought to extrapolate just a little bit—and Pat, you might be interested in this—on the potential of biotechnology.

He made a statement earlier in his remarks, that it is going to be a $100 billion industry by the turn of the century. Tell me how. I try not to ask questions I do not know the answers to, but I think that maybe the full committee might be fascinated with our answer to that. Just tell us what is going on.

Mr. **WALSH**. Well, Mr. Chairman, that was a figure that was the conservative figure of a study group that I participated in a few years ago. We tried to look into the future, and, there are several other studies going on also, using the Delphi method, and other methods.

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[19] See p. 255-64 for the above-referred-to letters.

One study is being done right now at Research Triangle Institute in North Carolina..

The CHAIRMAN. Now don't assume I know what the Delphi method is. What is the Delphi method?

Mr. WALSH. It is when you get experts together and get their prospective opinions on what is going to happen and why and when. The North Carolina Biotechnology Institute at Research Triargle Park is doing a Delphi method study in health and medicine right now. In health and medicine, biotechnology has revolutionized the drug and pharmaceutical industries. Drugs and biologics. I think almost every single biologic use, at the current time, and the development of new vaccines is reliant on recombinant DNA technology. So you have that whole renewed industry. In agriculture, the potential, I am told, is huge. For example, the ice-minus—the sprayed mutant bacteria could save 1 billion dollars' worth of crops from frost damage in the United States alone and that could be shipped around the world.

But even more significant, perhaps, because of what we are learning, because of what the scientists are learning, if you could get that ice-minus thing into the kernel of wheat, what would it do to the wheat industry? And say you could lower by minus 4 Centigrade the freezing temperature of wheat, where you could grow wheat, it would affect a 150-mile ban around the Northern Hemisphere—it would mainly affect Russia and Canada. And it would expand their wheat growing by 150 miles, and one question then is; What would that do to wheat markets?

Another question—and a question that I asked these experts that we had assembled about 1½ years ago was: How soon is this going to be practical? There were eight experts there. I am sure you would know their names. Jerry Still (USDA) was one of them. They agreed, unanimously, that within 5 years this will be possible. Now whether the Russians could apply it within 5 years, they had their doubts. But that is just one example of the use of the Delphi system for a prospective look at what will happen to agriculture because of biotechnology.

The pesticides, the biologically produced pesticides, have a probable salutary effect in all of agriculture, and for the environment generally, because they could replace a lot of the chemical pesticides. We know that some chemical pesticides cause damage to the ecology. But the firms like Monsanto are forbidden even to smallscale field test the new biological pesticides and that is the essence of my statement today.

The CHAIRMAN. You see the point, Pat. This is going on, and we had Mr.—I forget his name, but he was with the FDA. We have so many restrictions with respect to medication in this country. Things are still being held up that have been in use in Europe for 5 to 10 years.

Mr. WALSH. Mr. Chairman, a good example of that is this whole controversy over the pseudo-rabies swine vaccine.

The CHAIRMAN. That is correct.

Mr. WALSH. Swine are dying. You know, the Department of Agriculture issued the license; Rifkin sues everybody. Agriculture gets scared, pulls the thing back. In the meantime, a lot of pigs are dying. You know, the science is solid. What that fellow in Agriculture did was bad PR, but it was good science and good for the hog industry. Anyway, that is my interpretation of it, Mr. Chairman.

The CHAIRMAN. Well, this whole aspect fascinates me, and I apologize for making you extend your testimony.

Senator LEAHY. In this area, I think we are no longer seeing an arithmetical progression in science; we are seeing a geometrical progression. Our problem is how to keep up with that.

The CHAIRMAN. Well, thank you very much, and I hope your throat gets better. The pollen, though, will get better one of these days, I reckon.

Mr. WALSH. I hope so. Thank you, Mr. Chairman.

The CHAIRMAN. Is there any possibility we could go with any of the witnesses scheduled for this afternoon, save their time? Well, fine. If they are willing, I am willing.

Let me pose a question to James K. Champion of Riverdale Chemical Co. and president of the Pesticide Producers Association, Washington, DC; and Robert D. Shockey. Does the fact that there is some movement in the—would you be willing to testify now?

Mr. CHAMPION. Yes, sir.

Mr. SHOCKEY. Yes, sir.

The CHAIRMAN. Well, Mr. Champion, Mr. Shockey, and Mr. Miller. We will save you a little time and you can eat lunch in peace. Well, this is something that rarely ever happens around this place, the witnesses moving along, and I will say to you, as I said to them, that we would like to keep your oral testimony short, with the understanding that your full statements will be made a part of the record. We thank you for helping us out, and you may proceed.

STATEMENTS OF JAMES K. CHAMPION, RIVERDALE CHEMICAL CO., AND PRESIDENT, PESTICIDE PRODUCERS ASSOCIATION; ROBERT D. SHOCKEY, VICE PRESIDENT, PESTICIDE PRODUCERS ASSOCIATION; AND GEORGE MILLER, TRANS CHEMIC INDUSTRIES, AND CHAIRMAN, PESTICIDE PRODUCERS ASSOCIATION LEGISLATIVE COMMITTEE

Mr. CHAMPION. We appreciate your time, sir.

The CHAIRMAN. Thank you, sir.

Mr. CHAMPION. Mr. Chairman, my name is Jim Champion and I am president of Riverdale Chemical Co. of Chicago Heights, IL, and I am the current president of the Pesticide Producers Association.[20]

With me today is Robert Shockey, president of Drexel Chemical Co., Memphis, TN, and vice president of the Pesticide Producers Association, and George Miller, who is vice president of Trans Chemic Industries, Inc., in Secaucus, NJ, and chairman of our legislative committee.

Before going into our major concerns regarding the amendments to FIFRA, I would like to address the fears that PPA and our business concerns will obstruct either S. 2215 or S. 2346.

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[20] See p. 265 for additional material furnished by Mr. Champion.

Our business issues will have no effect on the environmental concerns addressed in these two bills. We do feel that though not apparent on the surface, business issues are interlaced throughout these bills, particularly in the sections covering reregistration and inert ingredients.

Attached to our written statement are our comments on S. 2215 for consideration by the committee. Due to the time constraints, we are only going to address two issues which have a direct impact on the ability of our members to conduct business and make legitimate business decisions.

I will discuss the first issue and Mr. Shockey will address the second.

The first issue involves the need for full industry involvement in the development of data requested under section 3(C)(2)(B) of FIFRA to support the continued registration of a currently registered pesticide product.

Under the current provisions of FIFRA, two or more registrants may join together to produce the data necessary to support the continued registration of a pesticide product.

The act neither addresses nor provides for the mandatory cooperation of registrants in the production of this required data.

It also does not provide for an equitable method of cost sharing between those participants associated with the production of this data. Our membership supports changes which would amend FIFRA to provide for: No. 1, the mandatory formation of industry task forces to develop the data required under section 3(C)(2)(B), data call-in notice.

Such task forces would be open to any registrant affected by said data call-in notice.

Second, the Administrator will immediately suspend the registration of any registrant who refuses to join that mandatory task force.

Third, the allocation of the cost associated with the development of the data should be divided among the participating registrants based on the following: The first 25 percent of the estimated cost for the development of the data to be divided equally among the participants with a maximum initial contribution from any one registrant of $100,000.

The balance of the cost to be shared based upon the market share of each participant as determined by an independent auditor on an annual basis during the lifetime of the task force. Each member of the task force shall be considered to have no less than a 5-percent market share of any given year.

Data developed by the task force shall be made available to subsequent registrants under the provisions of section 3(C)(1)(D) of FIFRA.

This approach to data testing will also meet the mandates of the 1982 FIFRA to conserve financial and testing resources. Only in an open, competitive market can American agriculture be assured of a supply of agricultural chemicals which are reasonably priced and not subject to a single supply source.

Mr. Chairman, I will let Mr. Shockey discuss the second issue.

The CHAIRMAN. Mr. Shockey, let me identify this gentleman sitting here. He is much younger than I am and he looks much younger. His name is Charlie Cunningham. We grew up together in Monroe, and I have just nominated him to be an honorary Senator for a few minutes. Is that all right?

Mr. SHOCKEY. Fine, sir.

The CHAIRMAN. Good; you may proceed.

Mr. SHOCKEY. Mr. Chairman, before addressing the need for a definition of compensation in the law, I would like to address the anticompetitive nature of the pesticide industry.

Studies have shown the anticompetitive nature of the pesticide industry. In Eicher, 1980, "The Farm Pesticide Industry" demonstrates that there has been a redistribution of profits in favor of chemical producers and away from formulators and distributors—the percent of each consumer-dollar going to basic chemical producers increased from 45 percent in 1965 to 66 percent in 1976. There also appears to be increasing forward vertical integration in the pesticide industry. About 50 percent of all formulators are now controlled by basic producers through either direct ownership or contractual obligation.

The top three agricultural chemical producers in the world account for 31 percent of the world pesticide sales. The top 10 account for 66 percent. Due to this noncompetitive atmosphere in the industry, and the barriers placed on a generic registrant before he can enter the market, PPA feels that the time is ripe for Congress to give a definition to data compensation in FIFRA.

After a patent has expired and a new company desires to enter that market, the new company must make a decision based on all potential costs affecting its business. In any other industry, including pharmaceuticals, you can define: first, the manufacturing process; second, raw material costs; third, cost of plant construction; fourth, general overhead; and, fifth, potential market. Normally, an informed business decision as to the new venture can be made but not in the pesticide industry.

Within our industry we have a big unknown: Data and potential data compensation which makes business planning impossible. FIFRA provides for data compensation but does not supply a definition of reasonable compensation. The arbitrators have no definition or guidelines upon which to judge reasonable compensation for data, and their decisions are final.

The only compensation case that we are aware of, that was decided by the arbitrators, to date, is *Stauffer* v. *PPG Industries*.

The decision provided for 50 percent of the cost of the data, $1,465,000, plus 15 cents per pound of technical product produced or purchased by PPG during the 10-year period of 1983 through 1992. Approximately $7 million.

It is important to note that 15 cents per pound is equivalent to 25 percent of PPG's net profits on the pesticide based upon the value of the product at the time of the decision.

To add to this was an arbitration cost of $48,000 for the arbitrators, and approximately $300,000 for legal fees. It is easy to see that this decision had no bearing on the sharing of the cost of data or of reasonable compensation.

In other laws, compensation is handled quite differently—Toxic Substance Control Act [TSCA] data costs are shared on market share basis. The Food, Drug, and Cosmetic Act permits generic registration without data compensation. Only in FIFRA do we have this question. We do not believe that the *Stauffer/PPG* decision promotes the original intent of Congress. We believe that Congress intended for a sharing the cost of data, not a reward to the original data submitter.

This is not an isolated situation. Recently, a second case has been submitted to the arbitrators, *Du Pont* against *Aceto, Griffin & Drexel Corp.* In this case Du Pont is asking $3 million from each of the companies, or 25 percent of its estimated development cost for data, plus a royalty of $1.50 per pound of pesticide containing linuron sold by the respondents during the first 5 years of sales. PPA believes that the time is ripe for Congress to define reasonable compensation for the use of data produced by another registrant.

This would guarantee that a competitive market is maintained in the industry and assure the American consumer of fairly priced pesticide products.

We suggest that a definition of reasonable compensation should encompass the following points:

First, data should have a compensable life of 15 years from the data first submitted to the EPA—as in the present law;

Second, the original data developer should receive compensation for up to 15 percent of the original cost of the data to cover incidental costs incurred during data development.

PPA proposes the following formula: Data compensation equals actual data cost times 115 percent times annual market share, and divide this by the 15-year life of data.

We believe that our formula provides reasonable compensation for the original registrant and does not preclude the entry into the market of a generic product.

This will keep competition in the agricultural business as opposed to current legislation and regulations which are fostering monopolies.

We are concerned with minor-use pesticides and pesticides used for minor crops because many of our members are regional formulators who must be concerned with all of the crops in their region. These regional formulators are losing agrichemical tools that their growers need to produce crops. We would be willing to work with the committee or anyone interested in the problem to see if there is a way to maintain these important tools for the American farmer.

Mr. Chairman, we thank you and the committee for this opportunity to present our views on the proposed amendments to FIFRA.

At this time we would be happy to respond to any questions you might have.

The CHAIRMAN. Thank you very much. Mr. Miller.

Mr. MILLER. I am just here to look pretty, sir.

Mr. CHAIRMAN. Well, you are doing it. All right. [Laughter.]

A couple of questions. I have a self-imposed policy, I mostly do not ask questions I do not know the answers to, but for the purpose of making the record, we emphasize certain points.

Let me ask the two or three of you: Is the present data compensation program performing as expected?

Mr. SHOCKEY. No, sir; it is not.

The **Chairman**. Well, why? I know you covered this, sort of; but why is it necessary to have any data compensation at all?

Mr. **Shockey**. Well, it would give the basic companies that are doing the research an opportunity to recover their costs for the research. And it would not give someone else completely a free ride.

The **Chairman**. Now are you hopeful of achieving some compromise that satisfies all of the parties in the matter you discussed?

Mr. **Champion**. Sir, we really feel that this, the two comments that we have made today, are a compromise position. The one that I have made on defensive data was agreed upon at one time by industry, but no longer has been agreed upon. The other one we feel is a compromise position on the data compensation. We think that it is very, very necessary for a definition of data compensation, and a logical way, and we figure that this is a way of, for the big basic producers to—no one getting a free ride and for them getting something out of it, but not to get something that makes it economically unfeasible for other companies to come in, and also, economically costly for the end producers, or the farm.

The **Chairman**. Well, how would you describe the status of the negotiations at the negotiations at the present time? In limbo or what?

Mr. **Champion**. It is very much one sided.

Mr. **Shockey**. It is basically a take-it-or-leave-it situation. This is the way it is. You take it or leave it. I think we have met twice, and both times, this was the discussion.

Mr. **Miller**. Mr. Chairman, you brought something up before that was interesting. In the present mode, we cannot make a business decision in order to say whether we ought to get into the market or not get into the market. The one variable that we do not know is data compensation, and if we can get some kind of definition, at least we will be able to make a reasonable business decision.

The **Chairman**. Well, let's assume that patent-term legislation were to be enacted into law and signed by the President. How would this affect the need for data compensation?

Mr. **Shockey**. Currently, it is impossible for us to enter a market on a generic product because of the up front sums of money that are being demanded, and the large data compensation.

Our company is being asked by Du Pont now to pay $3 million on the front for data, that we have no idea whether this is compensable data or not. They have just come out and said we have got 12 million dollars' worth of data that we have done the last 20–25 years. Also, they are asking for $1.50 a pound royalty, which is about the production cost of that product. That is about what it costs someone to produce that product.

There is no way that we can possibly pay this type of money and earn it back from profits in the business. So we are just excluded from the market.

Now the sad part is that the net effect of FIFRA from, say 1972 to the current date, has had on the agricultural-chemical industry, is that we are paying 35 percent more for commodity products in the United States than they are paying in overseas markets.

Our company started—for instance—in 1972, we were exporting items that we would buy in the United States and then sell outside.

Today, in Guatemala, I can buy methyl parathion, a product produced by Monsanto, for 82 cents a pound. In the United States it is sold by Monsanto for $1.55. Union Carbide sells carbaryl, manufactured in West Virginia for $1.85 per pound in Spain, and sells it for $2.55 per pound in the United States. So FIFRA has had this impact on many of the commodity pesticides. Now that is not all products but there is a great many. The bottom line in the whole data compensation issue is not recovery of costs for data.

The bottom line is major companies are saying can we keep these people out of the pesticide market? Elanco has had their Treflan patent for 19 years. They got a 17-year patent and 2-year extension.

Now they are claiming to have $90 million in data. The world market price on Treflan is half of what the Treflan price is in the United States. So this means that Elanco takes an additional $75 million—this is approximate—additional profits in the United States, over and above what they would be getting on world market price.

Now, if they can extend this for 10 years—you know, $75 million a year is a lot of money. This is the net effect of what has happened to FIFRA.

You have got history to look at now. It is not what is going to happen in the future. We can now say look back and see what FIFRA has done. This is a continuation of patent life without some type of relief. This will continue to allow major companies to monopolize the commodity pesticide market, at a time when the farmer needs to be paying less. The soybean farmer in the United States has to compete with the soybean grower in Brazil, paying this kind of price for Treflan.

Mr. CHAMPION. It also affects not only the farmer but also the regional formulators. There are many regional formulators in the United States and my company happens to be one of them.

When we can only buy one technical chemical, even though it is off patent, we have a problem of being able to compete in other areas besides the United States. It is just physically impossible for us to do that.

Even in the United States, if we do not buy a large enough volume of product, we may not be able to compete with some of the other companies that are in the marketplace because of their volume discounts and things like this.

So it makes it very difficult for a formulator to have just one source of supply. I mean it just makes it to a point where you have to rely only on one company and one company in particular, and that is very, very difficult to do.

Mr. MILLER. Mr. Chairman, going back to patent-term restoration, if the President were to sign the bill, it could actually follow that we could go along the same way the pharmaceutical bill went. The Senate passed a pharmaceutical bill that had generic registration in it; which meant, at the end of the patent term, all you had to do was prove that your product was equal to the product that was on the market, and then you could register your product.

The CHAIRMAN. Back in 1983, the formulators and the chemical companies reached an agreement. It seems to me that they ought to be able to work out something this year.

Mr. CHAMPION. The agreement that I mentioned for the defensive data on this, was the exact same agreement that was met in 1983.

Mr. SHOCKEY. If they only wanted to recover their cost of data, we do not object to paying them back, or paying a prorated share for the cost of the data. We can only get maybe like—the Atrazine market in the United States is 100 million pounds. Well, most smaller companies would only get 5 percent of that market. If we could pay a prorated share of the data, or pay for the cost of the data, there would be no problem with our member companies entering the market and you would have free competition.

But if we are required, as it currently is, to pay a share, or half—if we are the next guy that enters, we pay half of it, there is no way that the smaller company can have the dollars to enter this type market.

The CHAIRMAN. Why do you think that Guatemala, for example, the price is so much lower, or Spain—what is the logic in that?

Mr. SHOCKEY. Well, it is based on world market price. These Germans are selling methyl parathion for 92 cents, or 82 to 92 cents a pound. In the United States there is only one registrant or two registrants, and they do not have to sell that low in the United States. I mean, who can bring the product in, so there is no way of buying the product. If I could obtain the label—and I could obtain a label if I was not faced with huge data compensation claims—I could bring the product in and I would sell it for 90 cents in the United States

The CHAIRMAN. I see.

Mr. SHOCKEY. So, you would have a competitive market. There are several products that fall into that category.

The CHAIRMAN. I thought you identified a U.S. company that was selling the product.

Mr. SHOCKEY. They are. Monsanto sells at one price for the United States and another price outside, and Carbide has a price for the United States and another price outside, and Carbide's price—and I am not sure exactly what it is today, but historically it has been something like $1.85 outside the United States compared to $2.55 inside the United States.

The CHAIRMAN. Did you ever discuss this with, say, the American Farm Bureau Federation?

Mr. SHOCKEY. Yes, sir.

The CHAIRMAN. What did they say?

Mr. SHOCKEY. Well, they had other problems. There are not too many people aware of this impact, but if someone would look closely into the commodity market, there is tremendous impact, and right now, these companies are using all types of tactics to exclude us from these markets.

They will go overseas and they will buy—if a producer starts producing their product they will buy it all up. I have had Dow Chemical Co. go to Romania and offer them 10 percent more than I was paying for a commodity product, to prevent me from bringing it into the United States

So we are faced with—I have had Du Pont go into EPA and claim that at one time they had a contaminant in their product Linuron TAB and TAOB, and now that Du Pont has cleaned it up, EPA should not let these other products come into the market. So EPA, held me up, and I sat with $1 million in product, which cost me a quarter of million dollars in interest and other charges, for 1½ years, while I got my product cleared through EPA.

So we are harassed with FIFRA regulations, and all kinds of tactics that these companies are using to exclude the small formulator, or the small company from these large pesticide markets, the commodity markets.

Mr. CHAMPION. It boils down to economics, straight economics.

The CHAIRMAN. Most things do.

Mr. CHAMPION. Tens of millions of dollars.

Mr. SHOCKEY. Elanco with the extra $75 million a year U.S. profit can spend huge sums to keep others out of the U.S. Treflan market. Elanco is in Canada suing an Israel company. In Italy they are suing an Italian company and Drexel Chemical Co. in Memphis. Elanco now has made a complaint to one of the U.S. Government agencies to stop the importation of Treflan into the United States. So Elanco can spend $½ million or $1 million a year in legal fees; they are preserving $75 million in extra profit. So to spend, just to go out and just totally harass companies out of these markets is a standard practice.

The CHAIRMAN. Very well. You have raised some questions that are significant to me. I think I am going to pursue them not only with staff, but with some other folks, and I do not know whether I can be of any help or not, but we will see.

Any further comments that you may have?

Mr. CHAMPION. Thank you for your time, sir.

The CHAIRMAN. Well, thank you. You have contributed materially to the edification of this committee, and I do not want you to think that this comes to one Senator. It is for real around this place. The staff and the other Senators, as they get time they read these statements. We will be back at 2 p.m. Thank you very much. I appreciate it.

Mr. CHAMPION. Thank you, sir.

Mr. SHOCKEY. Thank you.

The CHAIRMAN. If there be no further business to come before the committee, we stand in recess

[Whereupon, at 12:02 p.m., the committee recessed, to reconvene at 2 p.m. this afternoon.]

AFTERNOON SESSION

The CHAIRMAN. The committee will come to order.

Senator Dixon.

Senator DIXON. Mr. Chairman, I am pleased to be here this afternoon as the Senate Agriculture Committee concludes its series of hearings on the reauthorization of the Federal Insecticide, Fungicide, and Rodenticide Act.

I want to thank all of our witnesses for their valuable counsel and for the time they spent preparing extensive testimony. With your assistance, we will craft legislation which will treat everyone equitably.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Dixon.

This morning, in an effort to facilitate the proceeding, we heard preliminarily from Mr. Champion, Mr. Shockey, and Mr. Miller, but there were two groups of people on the panel scheduled first at 2 o'clock. Therefore, we have Mr. Champion, Mr. Shockey, and Mr. Miller on my left.

Mr. Swan, vice president of Monsanto; accompanied by Mr. Brady; and John L. Hagaman, vice president of Dow Chemical of Midland, MI, on this side.

All right. I think you understand that your full statement will be part of the record and whatever summary you would make would be fine, and we would like to proceed.

STATEMENTS OF DONALD H. SWAN, GROUP VICE PRESIDENT, MONSANTO AGRICULTURAL PRODUCTS CO., ST. LOUIS, MO; ACCOMPANIED BY LARRY D. BRADY, VICE PRESIDENT, FMC CORP., PHILADELPHIA, PA; AND JOHN L. HAGAMAN, VICE PRESIDENT, DOW CHEMICAL CO., MIDLAND, MI

Mr. **Swan**. Thank you, Mr. Chairman.

My name is Don Swan, and I am group vice president for Monsanto Co.[21] To my right is Larry Brady, vice president and group manager of the Agricultural Chemicals Group for FMC; and to my left is John Hagaman, president of Global Agricultural Products for the Dow Chemical Co.

We are appearing for the Committee for Research and Development of Agricultural Chemicals, comprising 11 companies that invest in the research necessary to discover, register, and commercialize effective new pesticides for American agriculture.

We strongly oppose the Pesticide Producers Association's efforts to amend FIFRA's data compensation and arbitration provisions.

Under the current law, a follow-on registrant may register a pesticide simply by relying on data by a prior company who registered the same product. These data are generated only after a substantial investment of time and money. Congress therefore required follow-ons to pay compensation for relying on that data. That seems to make sense to us. The party which undertook the risks of developing data that enabled a pesticide to be commercialized should logically be compensated for a portion of the value of those data since they allow the follow-on to share in the fruits of their work. We realize that there may be disputes concerning the value of the data, but impartial experienced arbitrators selected by both parties can resolve any disputes over the proper amount of compensation.

The issue is not that we are trying to keep the follow-ons out of the marketplace; the issue is that we want to receive fair compensation for our data. Data compensation is a vital protection of the investment necessary to register new pesticides. PPA's very divisive amendment will jeopardize the compromise legislation agreed to after strenuous efforts by NACA and labor, environmental, and consumer groups.

Innovation is important to ensure that new pesticides are developed that are environmentally acceptable and more effective than those presently available with resulting benefits for food production and risk reduction.

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[21] See p. 277 for the prepared statement of Mr. Swan.

Developing new active ingredients is not easy, fast, or inexpensive. Very few new chemicals are registered each year. Twenty years ago, we could expect to find one chemical with pesticidal activity out of every 5,000 chemicals screened. Now we must screen 20,000. It typically costs a pesticide company $12 million, and takes 5 years just to develop the required data. EPA's regulatory review can delay commercialization by additional years.

Perhaps of equal significance is the scientific expertise necessary to develop the supporting data for registration. Residue, metabolism, toxicology, and environmental fate studies required experienced, highly qualified scientists and expensive equipment to satisfy EPA's rigorous protocols. These resources are not developed overnight to satisfy a one-time need. Instead, they are developed over time as a company commercializes the results of its innovative efforts.

We consider this data intellectual property, just the same as we consider patents, copyrights, and trademarks intellectual property. The total investment in commercializing a new pesticide can run greater than $30 million even prior to commercialization. These expenditures occur even before the product is on the market generating revenues.

If innovation is to continue, profits from products now on the market must be sufficient to support this major research effort. But a producer cannot generate such profits if a follow-on can quickly obtain its own registration by relying on the producer's data without paying its fair share. This price squeeze is aggravated by the erosion of patent protection that might otherwise be available.

For 17 years of patent protection are already reduced by 7 to 8 years typically necessary to develop required data and complete EPA review. Patent-term restoration legislation has been proposed to address this problem but does not now exist. FIFRA data compensation is therefore extremely important for continued innovation.

We are forced to conclude that PPA's real objective is to avoid paying meaningful compensation to the original registrant for the value of the investment required to develop the data-supporting registration of the product from which they seek to profit.

PPA frequently argues that FIFRA compensation benefits big producers over small ones. And that minimizing compensation is necessary for the little guy to compete. It simply is not true. Compensation is an issue between data developers and follow-on companies, not between large and small companies. Most of the little guys are formulators who already are exempt by law from compensation obligations. The real follow-ons are, in many cases, quite large, some larger than the basic producers. Others are backed by large foreign suppliers. Those companies are able to support a fair share of the investment necessary to generate the required data.

PPA also argues that it wants certainty so follow-ons know early on what their costs will be. We have no such certainty. When we start down the long road of developing a new product, we do not know what the total cost will be or whether the new product will succeed. In many cases, we do studies, and spend dollars for registration data on products that are never commercialized. Moreover, follow-ons can determine their cost early on if they wish. They can generate their own data. Or if a follow-on registrant wishes to rely on data submitted by another, it can initiate arbitration very early in its own planning process. This would allow a follow-on registrant to know with certainty what its costs will be before it commences manufacture.

PPA also argues that compensation extends to patent protection. This reflects a fundamental misunderstanding of patent laws and data compensation. Patents provide exclusive marketing rights while data compensation protects research investments.

If you run a manufacturing business and you invent a successful new product, you would expect other companies to enter the market once your patent expires. But you would not expect them to be able to come into your plant and have the benefit of your blueprints, research data, or other proprietary information. At least not without paying for the value of that information. That is what FIFRA compensation requires. It does not prevent our competitor from entering the market. But it does require that if they do so on the basis of our work and effort, they must compensate us. Compensation is critical to innovation. The current system was developed precisely because Congress was unable to develop a fixed-compensation formula that would be fair in the wide variety of circumstances that can arise. The system is now beginning to work and should be allowed to continue.

Thank you.

The CHAIRMAN. Thank you, sir.

Well, we have two points of view represented at the table here.

Let me raise this question. This suggested to me that pesticide producers be required to pay added compensation according to market share, plus the total cost of that of development.

Is this a fair formula, or should it include other costs such as advertisements and other marketing development costs?

Mr. BRADY. Mr. Chairman, we believe that the issue of access to the market and the timeliness of that access is related to the value of the data relevant across the generation.

The arbitrations today have taken two courses. One course being that given equal access to data, that the cost should be equally shared by the two parties. The other being, as you have just suggested, that the market share of the registrant coming in should mitigate against his paying an equal share.

It is our position that a party entering a market at a point in time has equal access to that market and equal capability to compete and therefore the value that derives to him by virtue of access to the data should be 50 percent.

In terms of the amount of information that is included in that valuation, we certainly believe that is based on individual cases. But we do believe in the event that the follow-on registrant is able to access the market much quicker by virtue of not having to spend the same time that we have spent in developing the data; that there is some associated value associated with that time period. And so, in both instances, I think we would support, first, an equal sharing of the cost. And second, that those issues are value rather than simply the older cost of data generation be included in an arbitrator's decision. But again that is the case that would be made by the two parties by an arbitrator and why we support in the final analysis arbitration as the logical view.

The CHAIRMAN. Can you comment on this, sir?

Mr. MILLER. Mr. Chairman, from our formula that we have proposed prior to this meeting here, we do give 15 percent as an extenuating circumstance for their risk in order to at least give them something additional besides the market share that we are asking for, and besides the fact that the data has a certain life.

Congress gave data 15 years, 10 years of total exclusive use and 5 years additional, a total of 15 years compensation. But that means each year the data loses a little value. And in losing a little value each year, why should someone else who is coming in now have to pay full value for something that is 15 years old?

The CHAIRMAN. I decline to sit as an arbitrator. [Laughter.]

Let us see. This bright young man here to my right, nobody has failed to see that he handed me a slip of paper, which says, "In the case of *Stauffer* v. *PPG Industries* was the compensation that the arbitrators approved fair in your opinion? And does this suggest that the current program is not working?"

Mr. SWAN. That current case is under appeal, and I am not personally familiar with all of the variables in it. So it would be very difficult for me to say whether it was fair or not. That there are a lot of variables that I am not familiar with.

But I think that they got a fair hearing, and both sides had a chance to present their case. So I am assuming that the arbitrator did his job properly. I see no reason to suggest that this—we are not familiar with the case, and it is under appeal so we could not address that issue. But we see no reason to suggest that that is evidence that the system is not working.

Mr. SHOCKEY. It appears to me part of it was fair; it was fair in that they would when they had another producer in the market, receive back one-half of their development cost.

Then the additional $7 million Du Pont would receive on Linuron at 15 cents a pound is a gimme, in my opinion. It is something that we are paying for that there is no basis for doing unless we are going to set up another patent system under FIFRA where they are going to be rewarded again.

Mr. HAGAMAN. I would attempt to address it in a response if I could.

Certainly the circumstance of issue is in fact that additional grant associated with the access to the market in advance of that which would have been possible by creating the data yourself.

The question of whether that was fair or not, or whether it was a gimme, I would suppose one would certainly have to address the fact that the arbitrator displayed a great sensitivity to the profitability of the follow-on registrant and, indeed, in structuring the formula for fair compensation, did so with the acknowledgment that that gave a highly profitable position to the follow-on registrant.

Mr. SHOCKEY. One point that they are making here is data, and they already have the 17-year exclusion rights of these pesticides under patent. Most of the data that we are talking about in the future would be expired by the time the patent, you know, had ended.

But during the life of the patent, the patentee also has other advantages—most of the pesticide patents are not ending in 17 years. The current Elanco Treflan patent is now 19 years old. They had a patent issued and then a reissue for another 2 years. Then during that same time, Elanco also patented a method of removing nitrosamine from the product. Now, they are suing companies in Canada and they are suing companies in Italy and they are suing companies in the United States for use of that second patent, which is perpetuating or extending that original patent for another 17 years.

So the patent issue is really another whole ball game. But again the small or new company looking at the ag label registration does not have a chance under patent law today, because there are process patents, composition of matter patents, various other patents that they continue to delvelop and file during the life of that original patent while we are restricted from even testing the pesticide during the patent life.

So, their chances of tying these products up for the life of the product are extremely good without FIFRA regulations. FIFRA regulations just continue giving them another tool to tie the pesticide up for the life of the product.

Mr. CHAMPION. In addition to that too, every time that there is a new use for a product that is developed, that 15 years will begin again. So you have that daily compensation continuing right on through. You can have this happen with a number of different products when new uses are provided for that product.

The CHAIRMAN. Give me an example. I do not know what you mean, new uses.

Mr. CHAMPION. Well, let us say you develop a product that is used on corn, and it is approved for use on corn. And you find out, over a period of time, that also it can be safe for use, let us say, on turf grass. That is developed—so you can develop an additional crop, let us say apples or oranges, and you go ahead and you get this, you have an additional 15 years use of that new data now that is developed that goes ahead and allows that product to be used on these new crops. So you have got an extension really to some extent of that product. It may have come off patent and someone may be able to get into the marketplace with corn, but they cannot touch it in the other areas until the 15 years or before the date of compensation.

One of the biggest problems that anyone has when they want to develop or get into the marketplace is this writing of a blank check, and giving it up. it is just an extremely difficult thing for any company to do when they are going into a marketplace, when they are going to go ahead and try to develop a product into the marketplace as a cheap product. It is just something that no sane businessman would want to do.

Mr. BRADY. Mr. Chairman, I can assure you that it is not our habit to delay taking products on which we have spent the kind of money we have spent into a market that we know is available, and it certainly is not by design that we do not create the data for new applications at the time of the original application submission.

It is only because the effort to create new markets for a product is a fairly extensive one and requires fairly extensive data. There is the legitimate question that says since the 15-year clock starts running on the original product, that the PPA or its members have access on that original application, and there is some, I guess, legitimate question as to why it should be shorter for other applications of the product.

In addition to that, I think, in terms of the patent laws, we would obviously, in pursuing patent term restoration, we would be hard pressed to suggest that the patent laws are advantageous to the ag chem business. I think it is even a fairly well accepted fact that the aggregate research investment of this industry is not being met with an adequate return. That is not to say that some companies are not being successful in the effort. But as many are failing as are succeeding.

Mr. **Miller**. Well, Mr. Chairman, I think that is a business decision that you have to make. If you are going to go into it, you understand you have a product, you have to take a chance as any innovator does, not only in the pesticide industry.

So, therefore, this morning we were talking about generic registration. We are not even asking for that. We are asking for a formula to be developed which we have one that could be submitted. That will take the guesswork out of us coming into the industry.

Mr. **Swan**. We live with guesswork all the time. Mr. Champion was saying that no sane businessman would invest money without certainty. We are investing over $100 million a year right now in research without any certainty that it is going to pay us any later results. Some do question our sanity.

But they do have routes for certainty. They have two routes where they can get that resolved ahead of time. We do not have any routes other than belief in ourselves.

The **Chairman**. Well, either Senator Lugar's bill nor mine addresses this aspect.

Senator **Lugar**. That is correct.

The **Chairman**. I ought to know the answer to this, but I do not. Do we even have jurisdiction over patent?

Staff. No. That is the Judiciary Committee.

The **Chairman**. Which one would?

Staff. Judiciary.

The **Chairman**. Judiciary.

And this matter is in the court on appeal. I will be glad to hear—this is very interesting to me. You fellows are the most devoted amiable adversaries I ever saw.

In the Senate, you may intensely dislike a guy, at least momentarily, sometimes permanently. But you always call him distinguished and able and my friend, and that is all the same.

But I think it is instructive and constructive. It is certainly helping me to have you here.

Yes, sir; you wanted to say something.

Mr. **Shockey**. I think the bottom line is you have got a history now since 1972; the beginning of FIFRA. FIFRA has increased the commodity price of many pesticides by 35 percent over world price on the products that are controlled under FIFRA and where companies are restrained from entering these markets. Monsanto has a product, parathion, where this is true. Most of FMC products have come from overseas. These major companies claim to be researching. These, in many cases, are not new molecules. They are simply bringing foreign technology over. I believe out of the last six or seven major products that FMC has had, they have all come from overseas. They are German or they are Japanese products. I am not sure they have one from their own research.

So their basic research, and when you say that you are taking a risk, it is not too risky when you are just taking an analog of another product that you know is successful.

Well, a lot of this R&D that they are doing is not really and truly R&D. Elanco, for instance, has one product that is 19 years, and one of the most profitable products, and they are certainly a capable research company, and they have not come up with anything near replacing this product. Now they are scared of that; they do not want to give it up.

So this is the primary reason. FMC is concerned because they have foridan that is about to expire. The concern is, primarily in my thinking, that they are going to lose these commodity products and they have nothing to replace them with. So that is unfortunate. You know, I would like for them to have something to replace it with. But there is no reason why the American consumer and the American farmer should continue to pay the price that we paid for the first 17 years of their basic research.

The CHAIRMAN. Except their argument being—and I am not taking sides in this thing—their argument is that to follow your suggestion—and if I misquote you fellows, please tell me—there "ain't going to be any research and development of these things."

Mr. SHOCKEY. I do not agree with that, sir. I think there were—most of the research now is coming many times from the countries that have some of the poorer patent protection. The products that I pointed out that FMC is getting are really coming from overseas. FMC years ago spent tremendous sums of money to synthesize for new compounds, and they met with very poor success in that area. They have been much more successful in obtaining these products from other countries where there was, in many instances, very little patent protection.

Mr. BRADY. I have a problem dignifying that with a response. The gentleman is misinformed and perhaps we should sit together——

The CHAIRMAN. I think so.

Mr. BRADY. And clarify his problem.

The CHAIRMAN. I think it is commendable that you are willing to sit down and discuss it publicly. I hope you will sit down and discuss it privately as well.

Well, thank you very much. I appreciate your appearing. Your testimony has been very helpful.

Our concluding panel this afternoon consists of Ms Maureen Hinkle, policy analyst with the National Audubon Society, Washington. All three are from Washington. Ms. Ellen Haas, and Erik Olson. Ms. Haas is the executive director of the Public Voice for Food and Health Policy, and Mr. Olson is counsel for pollution and toxic substances, National Wildlife Federation. All three are from Washington, DC.

Ms. Hinkle, if you will proceed with your statement, and then Ms. Haas and Mr. Olson. We welcome you and appreciate your contribution to our hearing.

STATEMENT OF MAUREEN K. HINKLE, DIRECTOR, AGRICULTURAL POLICY, NATIONAL AUDUBON SOCIETY

Ms. **Hinkle**. Thank you, Mr. Chairman.

I am here on behalf of three organizations: the National Audubon Society, the Environmental Defense Fund, and the Defenders of Wildlife. All three organizations have participated in FIFRA legislation, administrative hearings, and the implementation of the law since 1972.

Basically I will hurry through the testimony, which I hope will speak for itself.[22] But I want to clarify some points as a result of the hearings this morning.

The provisions of S. 2215 and S. 2346, which are similar, we support. There are three of them: preregistration access to health and safety studies, export notification of voluntary and withdrawn chemicals to foreign countries, and the definition of data gap. I inadvertently put the data gap definition in the wrong category, but it is one of the three provisions that are similar in both proposals.

There are four provisions of S. 2215 which we support totally: community right to know, revocation of tolerances, antiretaliation, and reregistration fees that are mandated.

There are four provisions of S. 2346 which we also support: inspection of establishments and warrants, penalties, other unlawful acts, and authority of States.

There is one change which I think needs to be made in other unlawful acts. If a registrant willfully falsifies all or part of his data submitted to EPA, or willfully submits false data, then he is subject to penalties.

We think that you should add "knowingly or willfully" so that it is similar to the knowing violation. for disclosure of information, given in the same piece of legislation.

Currently, a knowing violation of disclosure brings a $100,000 penalty. Even with the increased penalties that S. 2346 imposes for civil and criminal penalties, they do not serve as a useful deterrent for acts which are contrary to the public interest.

The fourth provision of S. 2346 which we support is one portion of section 1402 which would delete those registrations that a State does not use. Currently a State will register for special local needs something called 24(c) registrations. Sometimes these registrations are not used; they expire, they are deleted from the books. For all practical purposes, they have to stay on EPA's books, unless they are canceled under section 6 of FIFRA. This would just allow for automatic deletions of those registrations. It is really a very minor housekeeping provision.

We want to emphasize that we strongly oppose the State preemption language that is sprinkled throughout S. 2346 in section 1701 and section 1702. Section 1701 would limit sale and use, and section 1701(a)(2) would limit tolerances for States.

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[22] See p. 282 for the prepared statement of Ms. Hinkle.

Section 1702 would substitute current language with their revision of 24(c). Essentially they would delete the provision that EPA now has to approve the capability of States to register under 24(c). This requires a State not to abuse its authority to register pesticides for special local needs. There have only been two States which have abused that authority, and EPA revoked their State plan. This was just temporary until the States were made to understand the regulations and rules under which they are supposed to operate their plan.

Similarly, currently a State is not allowed to register canceled uses for special local needs. S. 2346 would allow State uses of canceled registrations under 24(c).

There was discussion this morning about Federal preemption. Peter Hutt urged national uniformity of regulation of levels of pesticide tolerances, and he gave EDB as an example of orderly regulation. We respectfully submit that EDB is a classic case of disorderly regulation.

I would like the record to show that the Environmental Defense Fund and Audubon asked EPA in 1975 to investigate EDB because it caused very early cancer in laboratory animals, 10 weeks as opposed to 20 months. Tumors were metastic in the stomach of these animals.

A year later, we submitted to EPA studies reporting that residues of EDB showed up in apples and in bread. We asked EPA to investigate whether or not residues might survive to other foods. Then, in 1981, EPA registered EDB for soybeans in the South, and that summer it showed up in ground water in Georgia. The registrant for agricultural chemical use of EDB immediately realized that this would be very bad for the farmers so they withdrew that use, and called EPA's attention to this ground water finding. The process was hurried up, and that EDB use was suspended from the market.

However, EDB did not reach national attention until a TV station did its own residue analyses of grocery shelf samples in 1983. At that point, States started to take management into their own hands.

I respectfully submit that we should look at why States and local jurisdictions seek to take regulation of pesticides into their own hands. It is not because they are trying to cause trouble, but they do feel that there has been some kind of failure at the national level. If there were more trust in the Federal EPA and in what the national standards were, then you really would not have such communities or States taking such action.

We would like to make some additions to a couple of changes; one on data disclosure to States. Everyone agrees that there should be data disclosure to States. We think there should be the same kind of sharing with foreign governments when it is in our own national interest. This would be discretionary with EPA and, for instance would probably only extend to Canada, but not to any other country that I can think of right now.

The other change is in inert ingredients. Both proposals have very complex listing requirements. We think the only change necessary, and Sterling drug interestingly supported this this morning, that the only need is to require an inert or chemically active ingredient on the label of a pesticide.

We also believe that the indemnities provision should be struck. We do not believe that the Government should pay companies when they have produced a product which is suspended because of a threat to safety and have stocks on their hands; $25 million was paid in this decade to two chemical companies for surplus stocks of a suspended product.

I do not want to take up any more time. We have a problem with the deadlines being too short, and we have a problem with standing for the public. This is in our statement.

Thank you very much.

The **Chairman**. The points that you just briefly alluded to are fully developed in your statement?

Ms. **Hinkle**. Yes, sir.

The **Chairman**. Very well.

Thank you very much.

Ms. Haas.

STATEMENT OF ELLEN HAAS, EXECUTIVE DIRECTOR, PUBLIC VOICE FOR FOOD AND HEALTH POLICY

Ms. **Haas**. Thank you, Chairman Helms.

I am Ellen Haas, executive director of Public Voice for Food and Health Policy, a nonprofit consumer research, education, and advocacy group active on food, nutrition, and agricultural issues.[23]

We are pleased to be here before you, and we are also part of the coalition of the campaign for pesticide reform. I might say also that I just served five terms as president of Consumer Federation of America, the Nation's largest consumer organization, which is also part of this coalition, and joins with Public Voice today in support of S. 2215, a bill that would create greater public protection from residues of inadequately tested pesticides that permeate our Nation's food supplies.

I think we have a unique perspective as a consumer organization, which is concerned about the safety and quality of our food supply.

We do praise this compromise legislation, which is the proud effort of 41 consumer, environmental, and labor organizations as well as 92 chemical companies. We feel that this legislation will provide much-needed critical improvements for FIFRA. These are changes that will lead to a reduction of the risk to public health posed by the widespread use of pesticides in agriculture products.

I am sure that there have been listings and listings of the many serious public health problems that have come to the national attention in recent years. We cannot forget really, just even in these last several months, California's recall last summer of watermelons tainted with aldicarb, and the recent recalls in Arkansas, Kansas, Mississippi, Oklahoma, and Tennessee of thousands of gallons of milk contaminated with the suspected carcinogen heptachlor. It is these kinds of incidents that we are hoping will be prevented by this kind of legislation.

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[23] See p. 292 for the prepared statement of Ms. Haas.

Pesticide residues, if present, generally pervade the food supply as an invisible danger, hidden from consumers who shop in supermarkets. Consumers cannot see pesticide residues on their fruits and vegetables.

Consumers who purchase food in the marketplace simply cannot protect themselves without strong government involvement. There is no easy way of identifying which pesticides have been used on their fruits and vegetables. You cannot see it, smell it, taste it, any lingering pesticide residue that might be there. Consumers are concerned when they hear of the national media stories about Government procedures that do not afford adequate protection.

The Food Marketing Institute every year does a study of "Consumer Attitudes and the Supermarket." At our recent National Food Policy Conference, they released their 1986 survey, and they found that the No. 1 concern of consumers who shopped in supermarkets or food stores around the country was pesticide residues; 75 percent of those polls believe that pesticide residues are a serious health hazard.

This consumer anxiety is very real, and there are many other public opinion surveys to substantiate it, and with basis.

According to a recent National Resources Defense Council analysis of fresh produce in San Francisco supermarkets, 44 percent contained measurable residues of 1 of 19 different pesticides, and 42 percent contained more than one chemical residue.

Unfortunately, because of these residues, consumers are routinely exposed to potentially significant health risks. Many pesticides in use have either been inadequately tested or have actually been found to be hazardous.

A 1982 study by the House Committee on Agriculture confirmed that there is an astounding dirth of adequate health data; 84 percent of registered pesticides lack adequate cancer tests, 93 percent lack adequate genetic mutation tests, and 70 percent lack birth defect tests. Consumers therefore cannot be assured that the pesticide residues in their food products are harmless.

We believe that S. 2215 does take important new strides forward in improving the status quo. The bill will remedy many notable weaknesses in the current program.

One, it will spur the EPA to develop an efficient schedule for registration of pesticides with lists of priorities. We do feel this schedule in effect is inadequate.

It will require data to support reregistration, and create a revenue pool to assist EPA in its responsibilities.

Establish expeditious EPA review and regulatory action on registrations that are based on invalid or faulty data.

Increase public access to health and safety data submitted by industry by permitting public perusal of such information prior to EPA action on registration.

Provide increased EPA authority to regulate inert ingredients.

Finally, Public Voice believes that these changes will be beneficial to the consumer as well as to the farmer and all those involved in pesticide applications. Consumers will be able to expect safer produce in the supermarkets as a result of better health data for pesticides and improved EPA registration procedures. S. 2215 should be passed by Congress and this committee as swiftly as possible.

Thank you.

The CHAIRMAN. Thank you, Ms. Haas.

Mr. Olson.

STATEMENT OF ERIK D. OLSON, COUNSEL, POLLUTION AND TOXIC SUBSTANCES DIVISION, NATIONAL WILDLIFE FOUNDATION

Mr. OLSON. Good afternoon, Mr Chairman. We appreciate the opportunity to testify.

My name is Erik Olson. I am the counsel for the Pollution and Toxic Substances Division of the National Wildlife Federation, the largest citizen conservation organization in the Nation, with over 4.5 million members and supporters nationwide.

We are a member organization of the campaign for pesticide reform which, as you noted, is a coalition of over 40 environmental, labor, and consumer organizations, which worked with NACA, the National Agricultural Chemicals Association, to agree on the compromise legislation that is before this committee, S. 2215.

S. 2215, as you know, is bipartisan legislation introduced by subcommittee Chairman Lugar and Senators Leahy and Proxmire.

While S. 2215, like the product of any negotiated compromise, does not contain every item on our "wish list," the federation strongly supports this legislation. I think it is rare indeed for any legislation to obtain the combined support of the pesticide industry and the environmental community. We hope that the hundreds of hours of tough negotiating that went into this legislation will help Congress to break the legislative deadlock that has delayed important broad-based amendments to the serious flaws in FIFRA.

This legislation embodies several much-needed improvements in FIFRA. It will require more complete health and safety tests to be done for all pesticides. Today, approximately 2.7 billion pounds of pesticides are placed in the Nation's environment each year. Many of these chemicals have never been tested for carcinogenicity, the ability to cause birth defects or reproductive failure, the ability to cause genetic mutations, or other effects.

The bill would give EPA substantial new resources to reregister each pesticide—that is to review the data and make a renewed determination of whether the pesticide unreasonably adversely affects the environment. Under the statute that takes into account the economic, social, environmental costs and benefits of the pesticide's use. These resources would be derived from the imposition, as you know, of a pesticide manufacturer reregistration fee which NACA has testified would not have any significant impact on the total cost of agricultural pesticides.

As the subcommittee is undoubtedly well aware, many pesticides were registered based on invalid or otherwise questionable data. We need only recall the scandal involving the IBT, Industrial Biotest lab, which falsified its tests on what amounted to between 35 and 40 percent of all the toxicological tests done nationwide. EPA found over 90 percent of IBT's tests invalid. Yet it has been estimated that the registrations of over 200 pesticides were based, at least in part, on IBT data. This legislation would give EPA new authority to cancel any pesticide registered with invalid or fraudulent data.

This legislation also would require substantial improvements in EPA's regulation of so-called inert ingredients in pesticides. EPA has identified about 100 of these inert ingredients that are suspected of being of "toxicological concern." These inert ingredients, by EPA's own admission, have been inadequately regulated, and may present serious environmental and public health threats themselves. They include benzene, chloroform, formaldehyde, vinyl chloride, hydrozene, and xylene which have been used as inert ingredients. The pesticide dicofol has been found to include up to 9 percent DDT as an inert ingredient and contaminant. S. 2215 would enhance EPA's authority to more closely regulate these inert ingredients.

In addition, the bill would streamline the unwieldy procedures for EPA's special review and cancellation that have tied up the program. These procedural hurdles have caused even known bad actor pesticides to remain in the marketplace for years, and to continue contaminating the environment, while EPA jumped through the unnecessary procedural hoops of the statute.

Another provision of particular importance to the National Wildlife Federation is the new provision regulating exportation and importation of pesticides. The provision will require detailed information to be sent to countries regarding the effects of certain pesticides exported from the United States. But it also ensures that food exported into the United States is safe by effectively prohibiting, with limited exceptions, the importation of food products with residues of banned or unregistered pesticides.

Finally, S. 2215 will substantially improve public knowledge and participation. The bill will amend FIFRA to include a community-right-to-know provision. Under this provision, chemical plants must disclose to neighboring citizens and local public authorities information regarding the health hazards of pesticides they are producing. In addition, the bill would require that scientific studies of the effects of pesticides on human health and the environment be made available before, rather than after, which is the case under the current statute, the chemicals are marketed.

This will allow environmental groups and others to comment adequately before EPA.

We at the National Wildlife Federation hope that the compromise negotiated will help Congress break the legislative deadlock on FIFRA.

I stand ready to answer any questions.

The CHAIRMAN. I think I know the answer to this which is why I am going to ask it. I do not like to ask questions I do not know the answer to.

Should there be national uniform tolerance standards on canceled pesticides?

Ms. HAAS. I will just comment.

You do start the national uniformity of standards, going real quickly into them for noncanceled standards. But I do see a problem with lack of action in general. So it may be the first step.

That may not be the answer—you have an answer that is different than ours.

Ms. HINKLE. The purpose of tolerances is to establish the floor. We believe if States want to be stronger than the Federal Government, for whatever reason, they should have that right.

Therefore it follows that should a State disagree with existing tolerances on canceled pesticides, a State could say it does not want any residues in its borders.

Mr. OLSON. Mr. Chairman, I am going to respond to that also.

I think that no person who has testified before this committee has suggested that the existing procedures and EPA's implementation of FIFRA have been adequate. I think that the traditional position of Congress—allowing the various and sundry States to protect their own citizens—ought to continue to exist.

The CHAIRMAN. If a farmer has followed the label instructions—and I am chairman of the Agriculture Committee, I have to look out for them—if a farmer has followed the label instructions carefully, should that farmer be exempt from liability?

Mr. OLSON. I will take a stab at that one.

I think it should be left to a court that is reviewing exactly what happened. Because if you include a generic exemption for anybody that follows pesticide labels—and again I do not think anybody that has testified before this subcommittee will suggest that all labels that exist are adequate—if the individual that is using the pesticide uses it in a negligent manner, even though the label may not prohibit that particular use, I think that it ought to be up to the court and it ought to be up to the States to determine whether liability is appropriate.

Ms. HAAS. I do not know what the position of the coalition is on this issue. But I would say, from Public Voice's perspective and working closely, as you know, on environmental and our many agriculture issues, and having participated in many hearings with farm groups in the States around the country, that the responsibility does not, in this instance, lie with the farmer. That the responsibility, if he has followed, or she has followed the label instructions, and if they are clear, that the responsibility really does go to the chemical companies. Whether or not you legislatively exempt the farmer from responsibility is another question. But, philosophically, I think all should be done to not put the burden on the farmer. But again that is a personal and not a coalition position.

Ms. HINKLE. As I understand it, FIFRA is silent on this issue. However, the law of product liability is such that the manufacturer, the registrant of the chemical in question, is liable. For instance, if the farmer has used EDB according to label directions and has done everything that EPA would require explicitly and implicitly, but he does contaminate his neighbor's ground water, he is not liable under the laws of product liability.

The chemical company is liable for any foreseeable use of this chemical all the way from manufacture to the actual use. Where the farmer has run into trouble, as I understand it, is a few States have explicitly enacted legislation to this effect.

The CHAIRMAN. You are saying the farmer is not liable?

Ms. HINKLE. Some States have held that the farmer is liable.

The CHAIRMAN. Yes.

Ms. HINKLE. And that is where this problem has now developed. There has been more debate about this.

But until these States enacted specific legislation, the law is quite clear that the farmer is not liable.

The CHAIRMAN. You know, I have caught myself going up and down the street just saying it depends on the specific matter.

I cited an example this morning, which had nothing to do with pesticides, of a small company down in Charlotte is about to be put out of business by EPA because it did not even know it was violating the EPA standard on emissions, you see, smoke stacks. And been cleared by the Mecklenburg Environmental Protection, whatever the name of it is. So, I am having a go-around with EPA.

To this day, this company cannot find out from EPA precisely what they did wrong. I think that is sort of a form of tyranny.

But I admit to being prejudiced. It does not make any sense to me for a farmer to be held liable where he has—you started to say something. I am sorry.

Ms. HINKLE. We agree with you.

Mr. OLSON. I would like to make a response to that.

I think as a general matter the State courts take that into consideration.

I have never heard of a case where the farmer was liable in that situation—I think it is mainly a product-liability-type question. It is the manufacturer.

The CHAIRMAN. Well, very interesting testimony and I have enjoyed having you and I appreciate your coming.

Thank you very much for your contributions.

Well, as that song says, "Everything's up to date in Kansas City," we have gone about as far as we can go.

There being no further business to come before the committee, we will adjourn.

Thank you very much.

[Whereupon, at 2:58 p.m., the committee adjourned, subject to the call of the Chair.]

APPENDIX

APRIL 22, 1986 HEARING

STATEMENT OF HONORABLE EDWARD ZORINSKY
A U.S. SENATOR FROM NEBRASKA

Mr. Chairman, I am glad that the committee is holding this series of hearings to consider amendments to the Federal Insecticide, Fungicide, and Rodenticide Act.

FIFRA is the primary Federal statute for the regulation of the registration, sale, and use of pesticides in this country. The effective regulation of pesticides is necessary to ensure the productivity of American agriculture and to control the spread of disease while protecting human health and safety and the environment.

Because the use of pesticides can have both beneficial and adverse effects, pesticide regulation involves very complex issues. The role of the Federal Government in this area has long been established.

The first Federal statute regulating pesticides was enacted in 1910. The Federal Insecticide, Fungicide, and Rodenticide Act became law in 1947. FIFRA has been subsequently amended numerous times. The amendments enacted in 1972 were among the most important.

The 1972 legislation broadened the scope of FIFRA and required, among other things, the reregistration and classification of thousands of pesticides that had been previously registered. Many of these chemicals had never been subjected to adequate scientific evaluation.

The 1972 legislation proved to be difficult to implement and was subsequently amended in 1975. Although the reregistration process was required to be completed in October 1977, virtually none of these pesticides had been reregistered by such date.

At the time legislation was considered in 1978, it was estimated that, because of budgetary restrictions, the registration process could require an additional 10 years.

It is now 8 years later, and the Environmental Protection Agency is still a long way from completing the reregistration that was initially required under the 1972 legislation.

Clearly, the failure to make substantial progress in completing this process is of great concern to pesticide manufacturers, consumers, environmental groups, and users of both agricultural and nonagricultural pesticides, as well as members of Congress. Legislation has been introduced to ensure that the Environmental Protection Agency proceed to complete the process in a timely fashion.

Senators Lugar, Leahy, and Proxmire are to be commended for their efforts to have this problem addressed during this session of Congress through their introduction of S. 2215. I understand that this bill is supported by the National Agricultural Chemicals Association and certain environmental organizations. In addition, I commend Chairman Helms for introducing S. 2346, a bill that is supported by the American Farm Bureau and other groups representing pesticide users and formulators, chemical specialties manufacturers, household chemicals makers, and the forest products industry. Together, these two bills contain numerous and sometimes diverse approaches to FIFRA reform.

In developing legislation to ensure the completion of the reregistration process, I believe that the committee must carefully consider the practicality of any time restrictions to be imposed upon EPA. It would be unwise to require that the agency meet unrealistic deadlines. Over-restrictive time limitations would only result in additional frustrations to the interested parties, the agency, and Congress, and would not serve the interest of the public.

Of course, the reregistration of thousands of chemicals will require adequate personnel and funding for EPA. One of the reasons why reregistration has proceeded at an unsatisfactory pace is that adequate funding has not been provided. It is, therefore, important that legislation reported by the committee ensure that adequate funding will be available.

The bill introduced by Senators Lugar, Leahy, and Proxmire, S. 2215, would provide funding through the imposition of a one-time registration fee on each active ingredient. The cost of this fee would be shared by registrants of pesticides that contain such active ingredient.

There is some concern that a fixed registration fee would ultimately be borne by the American agriculture at a time our farmers can least afford to do so. In addition, there is concern that a registration fee may reduce the variety of pesticides available to farmers. This is because the fee, when added to the high cost of required health and safety testing, may make it economically unfeasible for manufacturers to develop new pesticides or to continue the production and sale of existing pesticides if the pesticide involved has only limited uses.

The issue of funding is very important, and various methods to fund EPA's reregistration effort must be given careful consideration by the committee.

There are other issues involving the regulation of pesticides that are of concern to many interested parties. Some of these involve (1) minor use pesticides that are important to the production of certain crops and products, (2) conditional registration, (3) the regulation of inert ingredients, (4) availability of information in the registration process, and (5) the manner in which household chemicals, especially anti-microbials, are treated under FIFRA. Many of these issues are addressed in S. 2215 and in S. 2346.

I believe that the committee should give special attention to the extent to which farmers should be liable for damages resulting from their uses of pesticides. Currently, farmers are potentially liable for unforeseen damage caused by a pesticide even though there was compliance with all label requirements for its use. If farmers are found to be strictly liable for damages that may result from the prescribed use of pesticides, the cost of farming would greatly increase, and the increased cost could very well change the structure of agriculture in this country. This is because few, if any, farmers could afford to pay the high court awards for such damages or the cost of insurance to cover their potential liability for such damages.

Mr. Chairman, I look forward to reviewing the testimony of the witnesses at this series of hearings.

STATEMENT OF HONORABLE PATRICK J. LEAHY
A U.S. SENATOR FROM VERMONT

Mr. Chairman, I am pleased that these hearings on amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) are being held today. The issues encompassed by the legislation are varied and complex. Consequently, the committee will have to work diligently to complete a mark-up of the proposed amendments to FIFRA if we are to see them enacted this year. I understand that, in addition to S. 2215--the bill that I joined Senator Lugar and Senator Proxmire in introducing--the Chairman has introduced S. 2346. I look forward to reporting the strongest possible bill, and I will support all measures that modify the Nation's pesticide laws to better protect farmers, consumers, and the environment.

S. 2215, introduced by Senator Lugar, Senator Proximire, and me, can accomplish a strengthening of FIFRA. The bill represents literally years of effort on the part of several organizations concerned about safer uses of pesticides. Organizations supporting the bill include the Campaign on Pesticide Reform--a coalition of 41 consumer, environmental, and labor groups--and the National Agricultural Chemicals Association, whose membership includes some 92 companies.

S. 2215 amends the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the primary Federal law regulating registration, sale, and use of pesticides and certain other agricultural and household chemicals.

The bill improves the existing statute in several ways. First, S. 2215 would establish a schedule for completing the required reregistration of certain pesticides by the Environmental Protection Agency (EPA). The bill provides for a one-time fee for the reregistration of each active ingredient for which additional data is required. Proceeds generated by the fee will be used to defray the costs of the reregistration effort.

Under the provisions of S. 2215, expedited procedures would be established for EPA to review and take regulatory action on pesticide registrations that may have been based on false or invalid data submitted in the past. In addition, if a registrant willfully submits information known to be false in the process of registering a pesticide, EPA would be required to cancel the registration immediately.

The availability of conditional registrations for new products or for new major uses would be restricted under the provisions of S. 2215. Conditional registration will not be permitted if data concerning some of the more dangerous potential side effects of a pesticide would be required for its registration. In addition, conditional registrations must not materially increase the risk of any unreasonable adverse effect on the environment.

The public's right to know more about pesticide ingredients would be strengthened by S. 2215. A summary of health and safety data used to support applications for registration of active ingredients and certain inert ingredients must be developed by pesticide registrants and submitted to EPA. The data will be available to the public. In addition, the bill provides for increased public access to health and safety information submitted in support of the registration of new active ingredients and any initial food use of existing registered pesticides. Such access is allowed prior to any EPA action on a registration application but will be permitted solely for the purpose of public comment on the pending application.

S. 2215 gives EPA broader authority to regulate inert ingredients in pesticides. EPA's efforts will be focused on inert ingredients that pose the greatest risk to the environment.

The bill will also improve in several ways the existing statutory provisions related to export and foreign use of pesticides produced in the United States. The bill would require foreign purchasers of a pesticide to be notified of its cancellation, suspension, use restriction, or voluntary withdrawal. More strict labeling requirements are established for exported pesticides.

Under the bill requires EPA, within 60 days, to revoke or amend food tolerances on imported and domestically grown food when a pesticide registration is cancelled, suspended, denied, or voluntarily withdrawn.

With regard to registration cancellation procedures, S. 2215 establishes expedited procedures for conducting interim administrative or "special" reviews of pesticides. In addition, the bill provides for (1) increased employee protection in cases where an employee has initiated a proceding under FIFRA, (2) disclosure to appropriate State agencies of certain information acquired under FIFRA, and (3) authorized, coordinated inspection of laboratories.

Mr. Chairman, I look forward to seeing a FIFRA bill rapidly considered and reported from the Committee. I look forward to reviewing the testimony of today's witnesses.

STATEMENT OF HONORABLE ALAN J. DIXON
A U.S. SENATOR FROM ILLINOIS

Mr. Chairman, I commend you for calling this set of hearings on the reauthorization of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Congress enacted FIFRA in 1947 to protect our farmers from ineffective and dangerous pesticides. Over the years, the legislation has changed in many ways. However, our duty to protect our farmers and our citizens has not.

I am pleased to be here this morning to receive testimony from our panel of witnesses.

Thank you, Mr. Chairman.

STATEMENT OF HONORABLE PETE WILSON
A U.S. SENATOR FROM CALIFORNIA

Thank you, Mr. Chairman. It has been 8 years since the process which we are beginning today has been successfully completed. As you know and as others have commented, the last time Congress amended the Federal Pesticide Law--known as FIFRA--was in 1978. In recent years, many of us have become concerned about the adequacy of the statute and interested in improving the regulatory framework.

This interest and concern is obviously not confined to the members of this panel. Indeed, a diverse coalition of interested parties have spent numerous hours--working together--in an attempt to address and resolve some of the most difficult and contentious issues regarding this law, such as pesticide reregistration and cancellation, data disclosure and user liability. I believe that these groups are to be commended for their efforts which have produced two proposals for the Committee's consideration. And I am looking forward to their testimony.

This legislation is of particular importance to me and the farmers in my State. Not only is California the Nation's largest agricultural-producing State, but it is also our most diverse. Many of the fruits and vegetables and nuts upon which Californian farmers rely for their livelihood represent only "minor uses" for the pesticides produced by chemical manufacturers. In my view, it is critical that any reform of FIFRA does not create disincentives for manufacturers to provide safe and effective products for these so-called "minor use" crops.

I am pleased that we are beginning the task, today; commend you for holding these hearings; and hope that we will successfully conclude our work by year's end.

Thank you, Mr. Chairman.

STATEMENT OF HONORABLE MITCH McCONNELL
A U.S. SENATOR FROM KENTUCKY

Mr. Chairman, although not nearly as important as our work on the farm bill, the reauthorization of the Federal Insecticide, Fungicide, and Rodenticide Act is nonetheless an important and significant piece of legislation which makes some long overdue changes to FIFRA. The problem as I see it, though, is that some of the proposed changes aren't necessarily going to benefit the American farmer and may, in fact, burden him with an even greater degree of Federal involvement in his farming operation. The "compromise" which has been struck between the National Agricultural Chemicals Association and the Campaign for Pesticide Reform fails to address a number of critical issues which I feel must be reviewed if we are to make more than a cursory revision of FIFRA.

I'd like to call to my Committee colleagues' attention some of the issues that I hope today's witnesses from EPA will address. Nearly everyone agrees that the present EPA reregistration program is moving too slowly. Conversely, the NACA-CPR proposal to encompass the total reregistration process within 6-1/2 years is equally unrealistic. The proposal establishes a series of EPA mandated deadlines, without allowing the Administrator the flexibility to address potential problems. The NACA-CPA proposal is too severe since an active ingredient would be suspended if any data gap, no matter how insignificant, is not filled. Mr. Chairman, let me cite a couple of examples.

The Chairman will remember the blue mold crisis on tobacco about 5 years ago. Had there not been prompt and decisive action by the EPA in certifying a certain fungicide to prevent blue mold, thousands of small family farmers would have been driven out of business. Similarly, southeastern soybean growers were plagued by a fungus known as nematodes, which was a uniquely Southern problem. Only because of an emergency label for a certain product which kills the fungus were soybean growers able to plant beans. In each case, the kind of protracted reregisteration envisioned by the NACA-CPR coalition might not have allowed the aggressive testing taken by EPA. Especially during times of farm crisis, we must not take away a farmer's tools to fight the elements.

Although I share the concerns of the FIFRA coalition in dealing with inert ingredients in pesticides, I differ with the approach. Widespread exposure or use alone should not be a trigger or criteria to listing an inert ingredient. A pesticide containing an inert ingredient should be placed on the list for future testing only if a risk assessment indicated that a significant hazard may exist from the pesticide use. Although I believe that additional data should be generated for those troublesome inerts that might present a hazard to man or to the environment, the Administrator of EPA already has sufficient authority under FIFRA to require the generation of any necessary studies. In other words, why cause increased costly Government regulation when none is necessary.

Finally, Mr. Chairman, I am troubled by a statement the FIFRA coalition people made in my office. They all but said that any changes made to the bill introduced by Senator Lugar, the distinguished subcommittee chairman for this legislation, would cause the agreement to collapse. I frankly can't buy that. There are other issues which need to be addressed, including user fees, conditional registration, disputes over State and local authorities and public notification requirements. As a committee, we can't roll over and play dead when we're dealing with the legislation which has such a great impact on America's ability to produce food and fiber.

After all, Mr. Chairman, if there's a greater steward of the environment than the American farmer, I haven't met him yet.

Statement of John A. Moore
Assistant Administrator for Pesticides
and Toxic Substances
U.S. Environmental Protection Agency
Before the
Committee on Agriculture, Nutrition and Forestry
United States Senate
Washington, D.C.

April 22, 1986

Good morning, Mr. Chairman and members of the Subcommittee. It is with great pleasure that I appear before this Subcommittee for the first time in my tenure as Assistant Administrator for Pesticides and Toxic Substances at EPA. I will take this opportunity to discuss the Agency's major goals and accomplishments in improving the pesticide program. The goals - timeliness, scientific soundness, and openness of decision making - represent a sound, common sense approach to pesticide regulation. The Agency is committed to these goals and has put into place various administrative initiatives to accomplish them. I would like to highlight some of our recent accomplishments in pesticide regulation and then present our views on the statutory issues being considered by this Subcommittee. If the Agency is to attain fully its goals, there remain areas where FIFRA can and should be improved.

The reevaluation and reregistration of old pesticides is one of the Agency's primary responsibilities; it is also one of the most complex. The data bases for many of these pesticides are woefully inadequate and existing data have not been evaluated by current standards. It should not go unnoticed however, that the Agency's activities in the registration of new pesticides is significant. We have registered 56 new pesticides in the last 8 years with complete toxicology data bases.

The Agency has put into place an aggressive reregistration program which is proceeding at a steady rate. Last year, out of the 600 pesticides subject to reregistration, the Agency had evaluated data bases and issued registration standards for 98 of them; today 127 have been completed. To ensure that key data are available when we reevaluate a pesticide, we have accelerated the pace of the data call-in program for essential health effects data on food use chemicals. These key data include chronic toxicity, carcinogenicity, teratogenicity and reproductive toxicity. Such data have been required to fill clear data voids for all food use chemicals. (Approximately 350 chemicals were involved.) In addition, the Agency has also completed a pilot data call-in for 31 non-food use chemicals. This was a project in which registrants, rather than the Agency, identified data gaps and made commitments to develop the needed data. We expect to make greater use of this approach in the future.

The Agency also published a final rule last November which revised both the criteria and procedures for special review, the process by which the Agency evaluates the risks and benefits of chemicals which appear to pose significant risks. Unlike the old, hazard-only criteria, the new criteria allow the Agency to consider both hazard and exposure before beginning a special review. The effect of this change is to ensure that the intensive special review process is reserved for those pesticides which warrant the full risk/benefit review. Agency, USDA, registrant, user, and environmental group resources can be focused on those pesticides that really need close, careful scrutiny.

The Agency has also progressed in dealing with inert ingredients (ingredients which are not the pesticidally active ingredients) used in pesticide products. The Agency categorized the 1200 inerts into 4 groups: 1) inerts of immediate toxicological concern, 2) inerts with priority for testing, 3) innocuous substances, and 4) those about which relatively little is known. The criteria for identifying the 55 chemicals in the first category and the 51 in the second category, as well as the chemicals themselves, were reviewed and approved by the FIFRA Scientific Advisory Panel. A comprehensive strategy for evaluating inerts is in the final stages of Agency review; a draft version has been made available to the Subcommittee. This strategy parallels the reregistration program for pesticide active ingredients and sets in motion an orderly process for evaluating inerts, based on both toxicity and extent of exposure.

Finally, in developing a flexible regulatory program that tailors solutions to fit problems, the Agency is making greater use of its authority to restrict the use of pesticides to certified applicators. This regulatory tool is only effective, however, if the applicator certification and training programs are meaningful. A Certification and Training Task Force examined the relevant programs, identified their strengths and weaknesses, and made recommendations for change that clearly improve what is already one of the most effective federal/state partnerships in existence. The Task Force was composed of EPA, USDA, and state representatives with experience in and responsibility for running certification and training programs. I have established an Office of Training and Technical Support in my immediate office. That staff, with the help of our Regional Offices and the individual states, has already begun to implement the Task Force recommendations.

Reregistration

I'm proud of the fact that this country now has in place a pesticide regulatory program with clear objectives, strong leadership, and significantly improved technical competency. Even our harshest critics concede that we have an emerging record of results. There is however, an issue that casts a pall on Agency performance and continues to feed the public unease about the safety of pesticide use. That issue is reregistration of the older pesticides. In 1986, the prime concern is not how we are evaluating these products but the pace of the process. Both the NACA/CPR coalition and the FIFRA coalition strongly identify with this issue and have proposed, in different ways, to accelerate reregistration.

We at EPA applaud the fact that these groups and others with strong, contrasting views on FIFRA are taking a cooperative approach of identifying common issues and searching for effective remedies. However, until certain provisions are deleted, and others incorporated, we can not full support the bills.

The reregistration objective is a simple one: the evaluation of each old pesticide using the health and safety criteria in the current statute.

The milestones to achieve this objective are also straightforward.

1) Have current registrants formally commit to reregistration. Those who don't should be immediately taken off the market - we need offer no free ride.
2) Review existing data for adequacy and, as appropriate, require initiation of studies to support continued registration.
3) Set a time definite when current registrations will expire.
4) Evaluate data in support of registrations to determine whether the pesticide meets the "no unreasonable adverse effects" standard.
5) Issue a continued registration with any needed changes.
6) Begin the special review process for those chemicals, or specific uses, that cause a risk concern.

Under the current approach to reregistration, EPA issues documents called registration standards to describe its findings about chemicals undergoing reregistration. A registration standard states which existing studies are acceptable, and what new studies are needed to meet data requirements. A standard also evaluates chemical properties and risks, to the extent that data are available. It also describes those changes in labeling, composition, or other terms of registration the Agency believes are needed so that products will not pose unreasonable adverse effects.

While the process I have outlined is straightforward, it becomes formidable due to considerations of scale. There are about 600 pesticide active ingredients subject to reregistration. So far, EPA has completed about 127 standards, many of which served primarily to identify missing data. After data on these chemicals are received, the standards will have to be updated to reflect the new information. EPA invests large amounts of its own resources to identify gaps and inadequate studies - the process is very resource intensive. For example, to determine the adequacy of the existing data base for the approximately 420 active ingredients remaining at the end of FY 87, the Agency would have to review some 40,000 studies, which would require close to one thousand Agency work years. Moreover, much of this time consuming work is of a routine or clerical nature-- examining the existing studies to note variations from protocols and procedures now deemed acceptable, putting the data in a consistent format for efficient review, and noting which of the required studies have not been performed or obviously must be redone.

In the past months the Agency has been reevaluating whether this initial review and data formatting must be done by the Agency. For a new chemical not yet on the market, the applicant would identify, organize and submit a complete data set to support registration.

Clear and comprehensive data requirements for registration have been articulated since November 1984 when regulations (40 C.F.R. Part 158) were issued as regulations. Guidelines for testing and data development have been available since 1982. Good Laboratory Practice (GLP) regulations for health effects studies have been in place since 1984. In the last year the Agency has issued both guidelines for the format of data submitted to the Agency and standard evaluation procedures for several of the major data types. The pesticide industry is quite familiar with these documents. They provide comprehensive guidance on the data needed for registration, how to produce data of high quality, how to present those data to the Agency, and how the Agency will evaluate those data.

The real question, then, is: why are old chemicals treated differently than new chemicals? Why should EPA be performing the preliminary work of organizing the data base on old chemicals which registrants can and do perform for new chemicals? If we seek to accelerate the pace of reregistration, then let's conserve the Agency resources to focus on that part of the process that only it can do - evaluating data and determining the appropriateness of continued registration.

This new approach I have just outlined is consistent with the aim of both S. 2215 and H.R. 4513 (which is to be introduced in the Senate shortly) which is to achieve comprehensive identification of outstanding data requirements. While S. 2215 would place the entire burden of identifying data gaps on EPA, H.R. 4513 places the initial burden on registrants. This latter approach, with certain key modifications, provides a more equitable and cost effective approach to identifying data gaps. EPA would also place on the registrants the review of existing studies for validity and identification of data gaps. This process would be done in several phases in order to avoid a monumental influx of data at one time that would overwhelm Agency resources.

The Agency would first identify and then establish priorities for the pesticides subject to reregistration. We would set deadlines for the submission of applications for reregistration in two or three groups which would be dealt with sequentially. For each group the applicant for reregistration would make phased submissions; the first would include: an identification of data gaps and a commitment to develop the data within the timeframes the Agency has already specified, and the first installment of a reregistration fee. Sometime later, perhaps six months, the registrant would have to submit the second portion of the reregistration application. This second submission would include:

1) A summary of all existing data judged by the registrant to be of adequate quality and completeness, comparing the data to the current Agency guidelines for data development;
2) Reports of those existing studies, reformatted to conform to the Agency guidance on submission of data and flagged to identify adverse effects of potential concern;
3) A certification that raw data and other pertinent records are in the applicant's possession, and that appropriate laboratory practices were followed for all studies submitted;
4) A commitment to replace all inadequate studies necessary to support reregistration, within the times specified;
5) A second installment of the accelerated reregistration fee proposed in S. 2215.

Failure to comply with either of these two reregistration steps would result in immediate and summary cancellation. Data development progress reports would also be required, as in S. 2215. Finally, we would make clear from the outset that registrants must comply with all these reregistration 9 provisions by a date certain. A registrant of an old chemical would be given sufficient time to develop the complete data set. If after that period EPA had not received a complete and adequate data set, the existing registration would expire. If at any time after the submission of that data set, the Agency found studies to be lacking or inadequate, the registration would expire at that point.

The Agency would concentrate its resources on reviewing "flagged" data - the data registrants identify as showing potentially serious problems - following up on immediate problems identified through the flagging process, and evaluating pesticides with complete data sets. As these pesticides are evaluated the Agency would issue registration standards that summarize our analyses of the data and identify what changes in labeling, composition, or other terms of registration are needed to ensure that products will not pose unreasonable adverse effects. The Agency would also initiate the special review process for any pesticide that meets the criteria in our current rule. We estimate that, under this scheme, reregistration could probably be accomplished in an orderly way in no more than nine years.

Pesticides must have appropriate label directions and precautions to ensure that they are used safely, that the composition and packaging of the product are appropriate, and that any needed restrictions are in place. EPA may find -- as part of reregistration or because of other reviews -that changes in labeling, packaging or composition are needed to avoid unreasonable adverse effects.

Registrants usually comply voluntarily when the Agency seeks to impose such changes. However, in those instances where the registrant declines to comply with -- or even neglects to -respond to Agency efforts to obtain changes in the terms of registration, the Agency is faced with a serious implementation problem under the language in the current statute. Ordinarily, the Agency imposes these label changes through formal cancellation procedures under section 6. These procedures can be costly, as well as time consuming. Of course, registrants have a right to contest the Agency's views about changes to their products' registrations, but we think that EPA should have the option to use the more efficient rulemaking process to resolve these issues. While an extremely limited form of this concept appears in S. 2215, we believe that it should be explicitly acknowledged that the Agency be able to conduct rulemaking to require a wider range of changes to product registration, such as restricted use classification, geographic or seasonal limitations, or protective clothing, without having to go through the adjudicatory process. Further, S. 2215 would allow labeling changes through informal rulemaking unless such changes would have a major economic impact. Since it could be argued that most label changes may have such impacts, we recommend clarifying this provision.

EPA envisions the proposal operating in the following way. EPA would decide what conditions of registration needed to be changed, generally as part of the reregistration process. After notification to the registrant, the registrant would be required to notify the Agency within 30 days of its intent to comply with, or object to the changes. Failure to respond would result in summary cancellation. When the registrants object, EPA would have the option of using a rulemaking process like that described later in my testimony to effect the changes. This would entail the usual notice and comment procedures, where the views of registrants, users, and USDA would be taken into account. Registrants would be assured due process, but on an expedited basis.

Special Review and Cancellation

The early cancellation process was a formal, adversarial hearing procedure which did not provide either the regulated industry or the public with an opportunity to provide relevant information to the Agency prior to the commencement of hearings. In the mid 1970's the Agency created the special review process, a rulemaking-like procedure designed to collect information, encourage public and industry participation, and assist the Agency in making a decision whether to commence cancellation proceedings.

Unfortunately, this overall process for reviewing pesticides, deciding what changes to the terms of registration are needed, and taking necessary cancellation actions is very time consuming. Historically, the special review and cancellation of pesticide registrations under FIFRA have often taken more than three years, sometimes as much as 6 years.

The principal problem with the current cancellation system is that it consists of two steps, special reviews and formal adjudicative hearings, which repeat information gathering and decision functions.

Both S. 2215 and H.R. 4513 quite correctly attempt to deal with this problem. However, the Agency is unequivocally opposed to the approach S. 2215 adopts for resolving this issue. Certain features in H.R. 4513, particularly the criteria for initiating special reviews, are more acceptable. However, both bills leave the two-step process of special reviews and formal adjudications essentially unchanged, except for the incorporation of a series of deadlines. The deadlines in H.R. 4513 are somewhat longer than those in S. 2215. In both cases, these deadlines are apparently intended to reduce the length of these processes as simply specifying short deadlines does not promote efficiency or provide the new procedures needed to allow EPA to meet these deadlines. Thus, adopting either bill would result in missed deadlines, poor decision making and unnecessary litigation. In addition, S. 2215 actually limits the Agency's ability to act quickly and decisively when it has sufficient information to combine or forego steps in the special review process. This limits, rather than promotes efficiency.

S. 2215 also would make us use the old special review triggers which were abandoned because they did not allow the Agency to consider exposure in deciding whether to start a special review. This is a major step in the wrong direction! Under it, we would have to begin a special review even if we already knew that exposure was so low that risk was negligible. H.R. 4513, on the other hand, specifies criteria like those in our new regulation. Criteria that allow the Agency to consider hazard and exposure avoid this waste of our resources. If we are confident that a pesticide does not cause a real-world concern, we shouldn't be required to go through an expensive analysis of a hypothetical problem.

I believe that the intentions of both coalitions to expedite the special review and cancellation processes can be achieved by a more efficient means. Right now, we conduct a special review proceeding that is essentially like an informal notice-and-comment rulemaking, except that it has no binding effect if a person adversely affected objects to the Agency decisions. If objections are made, we then conduct a formal adjudication, with witnesses and cross-examination, to actually make the decision. We think that combining the most useful features of these two processes is the way to meet our mutual objectives.

We believe a hybrid proceeding which would add the benefits of cross-examination to the informal rulemaking process should be considered. Informal rulemaking is an effective way to collect information and make decisions; it also provides the public and the regulated industry with extensive opportunities to participate. Cross-examination allows detailed scrutiny of controversial positions or ambiguous data. The hybrid procedure would provide an opportunity for cross-examination on any issue involved in the rulemaking, but cross-examination would occur before the final rulemaking decision when the insights it provides would be most useful. Whatever changes are made to streamline the process, we wish to make certain that the registrant is given due process, that the process is made more efficient, and that the Agency's decisions are made on the basis of good science.

Cross-examination would take place after EPA issued a proposed rule. A limited opportunity for cross-examination would be allowed. This period could be tailored to the complexity of the issues involved, but could not exceed some fixed period, such as 30 days. Any person who had filed comments on the proposed rule could cross-examine others on any issue, although the time limits would require parties to focus on the issues they considered most important. The Agency would also have the opportunity to cross-examine any of the parties who had filed comments. (This is similar to the realities of cross-examination in U.S. District Court trials, where practical considerations force parties to focus their efforts on key issues.) The entire record of the mini-hearing would be incorporated into the administrative record. The Administrator would make his final decision on the rule based on the entire administrative record, including the record in the mini-hearing.

Since a hybrid procedure would combine the openness, efficiency, and speed of rulemaking with the opportunity for cross-examination, it would accelerate the process dramatically while still permitting detailed scrutiny of the important issues. We think this would make realistic deadlines attainable. We will, of course, continue to consult with the SAP and USDA, keeping them informed and involved in any process that would affect U.S. agriculture, as is currently done.

Inerts

Proper regulation of inert ingredients is among the Agency's top priorities. In the past, little attention was paid to ingredients of pesticides which are not pesticidally active. But more recently, it has been increasingly recognized that certain of these so-called "inert" ingredients can be as hazardous as some active ingredients. Thus, it is gratifying that both S. 2215 and H.R. 4513 outline substantial proposals for addressing inert ingredients in pesticides.

Both these bills propose the establishment of an inerts priority list of finite size, based on criteria designed to select those of greatest concern. We agree with this concept; limiting the size of the list enables the Agency to focus its attention on those substances that are most likely to cause health problems. The precise number of priority inerts is not so important as establishing this concept of a limit. However, we have already developed a list of inerts, so this requirement is unnecessary.

Both bills call for the development and publication of a Data Development Plan for each individual listed inert. We are opposed to this requirement. Preparing data development plans would be extremely lengthy and resource intensive, and we believe unnecessary. In fact, it is more than we normally do for active ingredients. H.R. 4513 also would establish a new scientific panel to review Agency risk assessments for inerts. The existing FIFRA Scientific Advisory Panel (SAP) already provides the Agency with an effective peer review system, therefore, a new Panel is not necessary.

Neither bill states clearly enough that the Agency would have authority to require sufficient data for the evaluation of inert ingredients. This authority must include the ability to require both short and long-term toxicological studies or exposure data when needed.

The third major element of the bills is the identification of certain inerts on product labels. We agree; we need clear authority and a simple process for the listing of certain inert ingredients of concern on labels when that information may contribute to the safe use of the product.

The Agency's draft "Strategy for Regulation of Inert Ingredients Used in Pesticide Products" details how we intend to go about dealing with potentially hazardous inert ingredients in pesticides. Let me summarize briefly now its main features.

Our objectives are to:

(1) Identify current and new toxic inerts in pesticide products and develop a regulatory strategy to minimize public health and environmental risks;

(2) Encourage the removal of toxic inerts when the risks are not justified by societal benefits and create incentives for substitution of less hazardous substances;

(3) Establish a testing program and requirements, as necessary, to address toxic effects and exposure; and

(4) Create public awareness of the existence of toxic or potentially toxic inert ingredients in pesticides so that appropriate precautions may be taken in their use.

As I mentioned earlier, an Agency-wide review group has reviewed the 1200 chemicals which are used as inert ingredients in pesticides, and has placed them in the following four categories:

1. Inerts with known significant toxicity (currently 55 chemicals).
2. Inerts with potentially significant toxicity, as suggested by structural similarity to known toxic substances (currently 51 chemicals).
3. Inerts which are not classified in lists 1 or 2, but can not be defined as innocuous (approximately 900 chemicals).
4. Inerts which have been determined to be innocuous, using GRAS lists and other similar lists of "safe chemicals" (approximately 200 chemicals).

Our focus is on those 106 inerts with potentially toxic properties. Our current effort is to learn all we possibly can about these chemicals and their use. Some of them are no longer being used, and many are inadequately identified in the Confidential Statements of Formula (CSF) now on file with the Agency. A CSF call-in is currently being planned to give us the detailed composition of pesticide formulations and enable us to do a preliminary exposure screen. Identification of further testing needs will involve a chemical-by-chemical review. Needed tests not already planned or underway will be required through a 3(c)(2)(B) data call-in. The Agency should have explicit authority in this area.

We have also initiated a new process for approval of new inerts or new uses of inerts. First a search is conducted of all to identify potential toxicity and reviews use information, if available, to estimate potential exposure levels. If an inert appears to be toxic, it will be subjected to testing before approval. The data requirements will generally be similar to the data requirements for active ingredients whenever appropriate.

To summarize our view on inerts, the Agency is already implementing a comprehensive strategy to deal with inerts. Although the EPA has adequate authority at the present time, the Agency would benefit from legislative clarification of our authority to list certain inerts on product labels and to require data necessary to evaluate them. To focus Agency attention on the critical issues, we favor limiting the size of the list of inerts. These legislative changes coupled with administrative improvements already implemented will effectively deal with the inerts.

Certification and Training

The abilities to classify a pesticide for restricted use and to prescribe limitations on its use via the label are essential regulatory tools. For this system to work well, however, applicators and those whom they supervise must have a high level of competence. Thus, one of the Agency's chief objectives, shared by USDA and our state colleagues, is to further develop and ensure a level of professionalism in certified applicators and those whom they supervise. This program is being built on the sound foundations established nearly a decade ago. The Agency is now implementing many of the recommendations of the Certification and Training Task Force. This will go a long way toward improving existing certification and training programs. Some of the recommendations can be best implemented by legislative changes.

First, Congress should give EPA the flexibility to specify the appropriate level of supervision a certified applicator must exercise in the application of a restricted use pesticide.

Second, Congress should provide a mechanism authorizing EPA and the states to enhance, through verifiable training, testing and experience, the level of competence of persons who work under the supervision of certified applicators. A number of far-sighted states, industry groups, and corporations are already upgrading the competence of commercial pest control technicians through training. It is important for EPA to have clear authority to require training and testing of supervised persons when the specific case so warrants.

Third, Congress should remove the prohibition in section 4 of FIFRA which forbids EPA from requiring the examination of private applicators after training in order to establish competence. Some states, on their own volition, have required examination of private applicators. These states have found that such testing reinforces the training and determines that the applicator has the basic knowledge on how to use restricted use pesticides safely. Removing the overt prohibition against EPA requiring testing would provide other states the encouragement, or at least remove the implied discouragement, to impose similar requirements. However, EPA does not intend to impose a national requirement in this area. Applicators should favor this, both in terms of their own personal safety as well as their liability for injuries caused by misuse.

Fourth, Congress should authorize the establishment of state pesticide dealer licensing programs. H.R. 4513 contains such a provision. Dealer licensing would enable EPA - with our state colleagues - to better control the sale of restricted use pesticides, particularly to non-certified purchasers. The dealer - the final link in the pesticide distribution system - is a logical point of control over access to restricted use pesticides and an effective point from which to communicate use restrictions and other important instructions to pesticide users. A uniform system of licensing in all states, which includes dealer record-keeping requirements, would enhance enforcement and lessen pesticide misuse. Some states which have implemented such systems have done so with little burden on the dealers.

Penalties

The penalty provisions found in the current FIFRA clearly need to be updated so that they are in line with the other environmental statutes that EPA administers. The present penalties lack significant deterrent value. For example, had the Agency been responsible for enforcing the recent pesticide incident in California involving the misuse of aldicarb on watermelons, the maximum civil action possible would have been a warning notice to the applicators. You will recall that dozens of our citizens sought medical treatment as a result of this incident. As another example, the top fine for a misformulated product that contained much more active ingredient than permitted by its registration would only be $5,000. Such a low penalty is certainly not going to mean much to a firm that grosses millions of dollars in pesticide sales. Although H.R. 4513 would increase the amount of current penalties, we recommend adding a judicial civil penalty in the amount of $25,000 per day per violation, which is consistent with other Agency statutes. Increasing the maximum penalties which the Agency may seek will not result in overly stringent effects on small businesses or those unable to pay large fines. The three factors that must be considered in imposing any final penalty - size of business, gravity of the violation, and effect on ability to stay in business - will continue to provide protection against excessive fines. I will be pleased to provide the Committee the FIFRA penalty matrix used by the Agency to illustrate this.

In addition to updating the penalty provisions of FIFRA, there are a number of actions - such as violations of emergency exemptions or EPA regulations, falsification of data by testing facilities and recommending use of a pesticide inconsistent with the label which the Agency believes should be considered violations of the FIFRA. Currently, these actions are not violations, but we believe they should be. H.R. 4513 contains provisions amending section 12 that go in the right direction.

In addition, FIFRA's criminal provisions should be revised. We would like to see stiffer penalties for knowing violation of the statute. In particular, maximum terms of imprisonment for registrants, commercial applicators, wholesalers, dealers, retailers and other distributors who knowingly violate the Act should be increased from one year (a misdemeanor) to two years (a felony). For private applicators and others not subject to the preceding, penalties should increase from the current $1000 fine plus 30 days imprisonment to $5000 plus one year.

We would also like to see creation of new penalities for life-threatening conduct, similar to those available under RCRA. These penalties are up to 15 years imprisonment plus a fine of up to $250,000 for individuals. Organizations should be subject to fines of up to $1 million.

Indemnity and Disposal Funding

Contrary to all other regulatory statutes, current law provides in sections 15 and 19 that if a product is suspended under section 6(c) and cancelled, EPA must both indemnify the owner of the pesticide for losses suffered as a result of the suspension/cancellation action (up to the fair market value of the product) and accept the pesticide for disposal at federal expense. In most other cases, the cost of regulation for environmental protection or other public benefit is placed on the regulated community, not the regulating agency. This is the case, for example, with defective cars. Manufacturers, not the taxpayer, absorb the cost of needed recalls. The Agency wants this legislative requirement for federal liability for the costs of indemnification and disposal stricken from the statute.

Registration and Reregistration Fees

There is considerable sentiment for having registrants pay the costs of the pesticide program, and we are exploring ways to recover these costs. We believe that users should pay for services provided them. Explicit legislative authority to recover registration and reregistration costs annually is being sought.

H.R. 4513 is silent on this issue and S. 2215 proposes a one-time fee to accelerate reregistration activities. The proposal in S. 2215 is evidence of a commitment to help complete the reregistration process. However, the proposed one time fee to accelerate reregistration can not support the continuing activity which would be required. We do, however, support the increased participation of industry, such as in identifying valid studies and reformating data for reregistration.

Under S. 2215, many of the pesticides that appear to be covered by the one-time fees have already been subject to data call-in, and the development of registration standards. It is EPA's assumption that these chemicals are also fully subject to accelerated reregistration fees to maintain their registration.

Finally, this reregistration fee proposal is very limited: an active ingredient would pay only once. Additional reregistration fees for that ingredient would be prohibited and other fees on registration or reregistration activities discouraged. This prohibition means that registrants would not pay for periodic reevaluations needed in the future. Moreover, the Agency is continually receiving applications for the registration of both new chemicals and new uses of old chemicals and expending resources for their evaluation. A one-time fee for reregistration clearly does not cover the cost of these continuing registration activities. The discouragement of additional fees in the "proposed legislative history" would have a chilling effect on our ability to go forward under our existing authority with fees which seem more workable than the reregistration proposal, and would seriously erode our incentive to investigate other possibilities.

The Office of Pesticides Programs is quite far along in analysis of a fee for certain registration activities. The fee would cover activities requested by registrants and could be imposed under existing IOAA authority. Our thinking has also included fees for Agency-initiated generic reviews of chemicals and costs of maintaining scientific staff.

There is also an EPA-wide effort to identify and evaluate potential fees for the services the Agency provides. There are important questions about allocation of fee revenues, the activities subject to fees and use of fees as policy tools rather than revenue sources only. For example, fees might be designed to encourage development of safer pesticides. Fees could also be quite helpful in alleviating the problems I described with certification and training and minor uses.

We believe your consideration of such questions could be extremely helpful, and are anxious to work with the Subcommittee to develop language for the FIFRA authorizing a fee structure that would recover full program costs.

Other Concerns and Summation

In addition to our major concerns about S. 2215 and H.R. 4513 there are several other issues. In order to maintain the quality of data supporting registrations, the Agency should be able to cancel registrations if they have been approved based on false, inaccurate or misleading data. While S. 2215 and H.R. 4513 both contain such provisions, more comprehensive and flexible amendments are needed. In addition, the Agency should have the authority to inspect commercial pesticide testing facilities and to require the keeping of appropriate records by such facilities. Both S. 2215 and H.R. 4513 contain provisions concerning testing laboratory inspection. However, H.R. 4513 would only permit the Agency to enter and inspect laboratories that have developed data to support registration and experimental use applications. It would not cover data being generated under data call-ins. In sum, we prefer a broader definition of facilities and a more complete recordkeeping and inspection authority than either bill proposes.

It is also important for EPA to be able to share pesticide data with the states. An amendment to section 10 of FIFRA is necessary to allow EPA to disclose to state governments information that cannot be disclosed to the general public under the current law (e.g., production data, analytical methods, formula information). We also agree that a state should be able to obtain data from EPA under FIFRA only if state law provides as much protection as FIFRA against disclosure of the data and against unconsented use of the data by others to obtain registrations. It is not clear to us, however, how the cooperative agreement approach proposal in S. 2215 would enable disclosure of such data to the states. More importantly, we strongly believe that the federal government should not be liable under the Tucker Act if, after EPA properly discloses data to a state, the state improperly discloses data to another person. Thus, the Agency opposes the specific provisions in S. 2215 and H.R. 4513 that would make the Federal government liable for state actions.

In addition, the Agency is also interested in reevaluating FIFRA section 10(g). While we support the goals of this section -- protection of domestic industry from unfair international competition -- we would like to explore the possibility of achieving these goals by working with the U.S. Trade Representative and other affected agencies to explore appropriate bilateral and multilateral agreements for the protection of proprietary rights to data.

Both bills also propose a significant and unnecessarily complex expansion of the export notification system. The notifications which EPA would be required to submit under this legislation would far exceed those required in the FAO International Code of Conduct on the Distribution and Use of Pesticides (1984), the OECD Information Exchange on Hazardous Substances (1982), or the Provisional UNEP Information Exchange on Potentialy Harmful Substances (1982). These sections should be reevaluated. However, since Provisional International agreement has been achieved through the United Nations Environment Programme on the current system and until we have had time to evaluate the effectiveness of that agreement we belive the system should remain intact.

In addition, we do not support the proposed changes to Section 17 in S. 2215 relating to international cooperation. We do participate in international activities to the extent our resources permit, and we do provide assistance to developing countries on a case by case basis. The Administrator is interested in determining what additional steps EPA can take in assisting developing countries, and he has recently assigned a top level EPA official to develop ideas for this purpose. The Agency supports the intention of these amendments, but would emphasize that the problems of pesticide misuse in developing countries can only be resolved through strengthened national programs in the developing countries on the one hand and appropriate multilateral action with the developed countries on the other. The voluntary Code of Conduct on the Distribution and Use of Pesticides developed by the Food and Agriculture Organization of the United Nations is an example of such multilateral action which puts this division of labor in a proper perspective. We also believe that the nature and extent of the bilateral assistance activities proposed in S. 2215 would be implemented more appropriately by the Agency for International Development.

H.R. 4513, on the other hand, would limit EPA's international activities to pesticide research and would exclude participation in international efforts to improve pesticide regulation. We also oppose this change, since such activities are key to improving the use of pesticides world-wide and maintaining the quality of foodstuffs exported to the U.S.

S. 2215 also proposes a new section to require tolerance revocation after a cancellation action occurs. We do not support this amendment since we have already developed a policy which achieves the same goal - elimination of available dietary exposure to cancelled pesticides - and which should resolve this problem quite effectively. Furthermore, the issue of tolerances and their revocation is within the jurisdiction of the Federal Food, Drug and Cosmetic Act, not FIFRA.

The FIFRA also contains a provision that postpones the effective date of final regulations until 60 days of continuous Congressional session have elapsed. In practice, this may mean a delay of as much as six to nine months, before a final rule becomes effective. We believe that the normal procedures required by the Administrative Procedure Act for informal rulemaking provide sufficient opportunity for review of final rules before they become effective. Thus, we recommend this provision of FIFRA be eliminated.

S. 2215 would expand the scope of 3(c)(2)(B) suspension hearings to include the validity and reasonableness of the data which the Agency requires under section 3(c)(2)(B). We strongly oppose this expansion of the matters to be resolved in such a hearing. We believe that current law provides adequate opportunity for registrants to challenge the validity of the Agency's data requirements in court. We also believe that the changes to conditional registrations proposed in S. 2215 are unnecessary since EPA has already adopted stringent criteria for these registrations.

Finally, as a housekeeping measure, the Agency suggests that FIFRA be amended to permit the automatic cancellation of federal registrations when corresponding state special local needs registration are cancelled or expire. Also, H.R. 4513 includes a provision which would increase the level of effort for work at the Beltsville, Maryland facility on biological testing of pesticides, especially disinfectants. We oppose this provision, and believe that such work is best supported by the commercial concerns which benefit directly from the data.

In summary, the most important pesticide issues before us are efficiency in the reregistration and special review programs, effective regulation of inerts, competency of certified pesticide applicators, adequate enforcement responsibility, and realistic fee structures for the pesticide regulatory activities that must be performed by the Agency.

While we are pleased that S. 2215 and H.R. 4513 focus on these issues, we believe that the Agency's alternative proposals outlined here today would achieve our shared goals more effectively.

With these comments, I am concluding my prepared statement. I am hopeful that with this constructive start, we will have a fruitful legislative process in 1986. Agency staff will be glad to provide any technical assistance you may need.

[The following material was submitted by Dr. Jack Early, President, National Agricultural Chemical Association]

EXECUTIVE SUMMARY OF THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT AMENDMENTS OF 1986

The following summary describes proposed legislation mutually agreed upon by the Campaign for Pesticide Reform and the National Agricultural Chemicals Association. The legislation was introduced on March 20, 1986 as S. 2215 by Senators Lugar, Leahy, and Proxmire.

Reregistration and Revenues

The proposed amendments are designed to establish a schedule for completion of the reregistration of pesticides, currently required by FIFRA. They initially require EPA to develop two lists of pesticide active ingredients for reregistration. A priority list of 300 active ingredients scheduled for reregistration must be developed within sixty (60) days of enactment, followed within thirty (30) days thereafter by a second list of the remaining chemicals.

Within eighteen months of enactment for the first list, and within twenty-four months of enactment for the second list, EPA is required to fully evaluate the existing data supporting registrations for the active ingredients and to issue notices to registrants to fill any outstanding data requirements. Registrants then have up to four years to complete the studies required, with an exceptional circumstance extension of up to two years for unanticipated delays. Failure to submit data within such deadlines will result in suspension of registration. Following submission of the studies, EPA has one year to reregister the pesticide.

The proposal provides for a one-time fee on active ingredients to assist EPA's reregistration effort. The fee is divided into two parts. After an initial opportunity for registrants to voluntarily cancel registrations which they do not wish to reregister, a fee of $50,000 is assessed on each active ingredient when EPA issues its notification of outstanding data requirements for that active ingredient. Another fee of $100,000 is assessed when the registrants submit the required data. Lesser fees may be assessed for registrations of active ingredients not used on food or feed. The reregistration fee is apportioned among active ingredient registrants and formulators are exempted from paying the fee.

False or Invalid Data

The proposed amendments provide expeditious EPA review and regulatory action on registrations that are based on false or invalid data.

First, the amendments require EPA to issue a notice of intent to suspend and to cancel the registration of a pesticide if, prior to the effective date of the amendments, the Administrator has previously determined in its Industrial Biotest validation process that data submitted by a registrant to the Agency in support of an existing registration were invalid, have not been replaced or will not be replaced by April 1, 1988, and are material to the registration.

Second, if EPA determines subsequent to enactment of the amendments that invalid data have been submitted by a registrant in support of a registration, the amendments also authorize EPA either to require the registrant to submit valid replacement studies on an expedited basis or to issue a notice of intent to cancel the registration. These amendments are designed to allow EPA to take action on registrations in any future circumstances, such as occurred with Industrial Biotest (IBT), where the Agency discovers that pivotal studies, previously thought to be valid in justifying a product's registration, are in fact invalid and the continued use of the product may cause an unreasonable risk.

Finally, in contrast to instances of data invalidity addressed in the two previous amendments, the proposal also provides that EPA shall immediately cancel a registration if a registrant willfully submits material data known to be false in support of the registration.

In all three of these situations, EPA is authorized to conduct an abbreviated hearing under FIFRA section 6, to be concluded within seventy-five (75) days after receipt of the request for such a hearing upon notice of cancellation. The hearing will address only a limited number of issues relevant to whether the data are false or invalid and the appropriate impact on the registration.

An amendment to FIFRA section 12 also states that willful falsification of data or knowing submission of false data are unlawful acts, subject to civil and criminal penalties.

Conditional Registration

The proposed FIFRA amendments restrict the availability of conditional registrations for new products and new major uses.

The proposal states that EPA will not grant a conditional registration for a new use or active ingredient where the data concerning chronic toxicity (oncogenicity, reproductive effects, and mutagenicity), neurotoxicity, or teratogenicity are required for registration, such data have not been submitted, and the data requirement was in effect at the start of data development. Additionally, EPA may amend conditional registrations for existing uses to allow revisions of labels--for example, application methods, efficiency claims, and safety instructions--except if such modifications introduce uses prohibited by the amended statute.

The restriction on conditional registrations is refined further by amendments to FIFRA section 3, stating that such registrations must not materially increase the risk of any unreasonable adverse effect on the environment, registrants must provide all additional data required for the proposed additional use, and the additional use is in the public interest.

Public Right to Know

The proposed amendments direct registrants to develop and submit to EPA a summary of health and safety data supporting their registered active ingredients and on priority inert ingredients. Such summaries will be made available to local communities and the public on request. The priority inert ingredients requiring summaries are those 50 to 75 inert ingredients to be listed and regulated under other proposed FIFRA amendments described below. The summaries, similar in substance and form to Material Safety Data Sheets under the Occupational Safety and Health Act, must be developed within 120 days of enactment of the amendments. EPA may require modifications to the summaries as needed.

Registered establishments must also obtain and make available to the public on request such summaries on active and inert ingredients used in the establishment.

Finally, the amendments clarify that registrants must provide a list of plant locations in the United States where active ingredients are produced and to make this list available to the public on request.

Preregistration Access to Data

The proposed amendment expands public access to health and safety data submitted in support of registrations on new active ingredients and initial food uses of existing registered pesticides. Access to such data is allowed prior to EPA's action on registration applications and is permitted solely for the purpose of public comment on pending applications. The amendments allow access immediately following EPA's publication of receipt of the application for registration and, once the supporting data is disclosed, allow sixty (60) days for public comment. The data will be made available in the offices of EPA or authorized state agencies upon submission of an affirmation that the data reviewer is not acting for a pesticide company and will not intentionally or recklessly violate other restrictions in the Act to protect confidentiality. Comments may quote and discuss the data and may be exchanged for peer review, but will not be made public until after a registration decision has been reached and in compliance with section 10 confidentiality provisions. The data shall not be used for commercial purposes and penalties are provided for wrongful use of data under both FIFRA and other Federal laws.

Inert Ingredients

The proposed amendments give increased authority to EPA to regulate inert ingredients in pesticides. It requires EPA to develop a priority list of fifty (50) inert ingredients within ninety days of enactment and allows expansion of the list to seventy-five (75) inert ingredients fifteen months after enactment. Criteria are provided to focus the list on inerts with potentially the greatest risk to health or the environment.

Once an inert is listed, EPA is required to develop and publish within one year a plan on what toxicity studies must be conducted and the deadlines for submission of such studies. Once the data development plan is published, pesticides containing listed inerts must list such inert ingredient on the product label. Studies required by the data development plan must be submitted in no more than four (4) years and must be reviewed and appropriate action be taken by EPA within one year of receipt.

The amendments also establish requirements for testing inert ingredients used to replace listed inerts, submission of amended confidential statements of formula, registration of pesticides containing listed inerts, labelling of listed inerts and misbranding provisions, and data development cost allocation.

Export of Pesticides

The proposed amendments address a number of issues in the export and foreign use of U.S. pesticides.

First, the proposal expands the current notice requirements of registrants to inform, at least annually, foreign importers and importing countries about their products in international trade whose registrations are cancelled, suspended, are restricted use pesticides, are not registered for any U.S. use, or have been voluntarily withdrawn for health or environmental reasons. Export cannot proceed until the notice and evidence of its delivery have been provided to the EPA and made available to the public. Notices will identify the exporter, foreign purchaser, the appropriate regulatory office in the importing country, and a clear statement of the reason why the product cannot be legally sold in the U.S. or is a restricted use. EPA must annually provide similar notices to foreign governments and appropriate international agencies.

Second, the amendments require exported pesticides which are substantially similar in composition and use pattern to pesticides registered in the U.S. to have labels containing the same health, safety and hazard precautions as U.S. products, unless such precautions on the label are in conflict with the law of the importing country. The labels are to be written in an appropriate language and describe on the label those requirements that are handled on U.S. labels solely by reference to U.S. law.

Third, the proposal requires EPA within sixty days to revoke or amend food tolerances on imported and domestically grown food when a pesticide registration has been cancelled, suspended, denied, or voluntarily withdrawn, unless any of such actions were due solely to environmental effects. The action on the tolerance may take into account consumption of food in commerce, use of existing stocks, and unavoidable environmental contamination.

Finally, the amendment encourages EPA to assist foreign governments in establishing comprehensive pesticide programs and allows EPA to inspect and regulate the maintenance of records by pesticide exporters.

Cancellation Procedures

The proposed amendments establish expedited procedures for EPA's conduct of interim administrative or "special" reviews of pesticides, and sets time limits on those reviews and product registration cancellation hearings. The amendments also permit certain modifications of labels by informal rulemaking unless they are equivalent to a cancellation, render the product unmarketable or have a major economic impact.

With respect to interim administrative reviews initiated after January 1, 1986, the proposal establishes criteria for initiating a review on the basis of levels of risk and permits consideration of currently available exposure data. The absence of exposure data will not delay or preclude initiation of reviews. When administrative review triggers are exceeded, EPA shall immediately notify the registrants, who shall respond within thirty (30) days to the Agency's assessment that the trigger has been activated. Once a notice of a review is formally initiated, the amendments further provide that the interim administrative review must be completed within one year. Key elements of the schedule call for a ninety (90) day public response to the EPA's notice of an interim administrative review, ninety (90) day EPA review of public comments and issuance of a proposed decision, thirty (30) day Scientific Advisory Panel review of the proposed decision, and sixty (60) day deadline thereafter for final EPA decision. The overall time limit of one (1) year may be extended up to an additional year for exceptional circumstances and under certain limitations.

With respect to product registration cancellation hearings, the amendments establish a time limit of six (6) months for hearings conducted subsequent to an interim administrative review and twelve (12) months for hearings not following such a review. In either instance, a hearing may be requested by any adversely affected party, including those without an economic interest (e.g., environmental or labor organizations). The amendments prescribe the conditions under which EPA may grant a hearing and the hearing procedures. Essentially, a hearing which follows an interim administrative review must be conducted on the following schedule: the hearing must commence sixty (60) days from appointment of the Hearing Examiner and conclude sixty (60) days thereafter, briefs must be filed within twenty (20) days of transcript receipt, and the Examiner's recommended decision made twenty (20) days from submission of briefs. The schedule may be extended for up to 180 days in exceptional circumstances.

Employee Protection

The proposed amendments require that no employer may discharge or otherwise discriminate against any employee with respect to the employee's compensation and conditions of employment because the employee or a person acting at the request of the employee has initiated a proceeding under FIFRA, testified, or participated in such a proceeding. EPA is instructed to implement these protections in a manner consistent with a similar section of the Toxic Substances Control Act.

Data Disclosure to States

The amendments permit EPA to disclose to appropriate state agencies any data or information acquired under FIFRA, if the state and EPA assure that the owner of the data will receive no less protection with respect to disclosure and use of the data than is provided under FIFRA. The amendments additionally provide for remedies if improper disclosure is made.

Inspection of Laboratories

The amendments authorize EPA to inspect relevant parts of laboratories, related books and records, and data supporting applications for experimental use permits and registrations. Additionally, the provisions require EPA to coordinate such inspections with actions taken under other Federal laws to avoid duplication.

Data Confidentiality

The proposal provides legislative history to clarify the provisions of FIFRA section 10(g). Essentially, the Committee Report would state that data may be discussed, quoted, disclosed or otherwise communicated, but with conditions sufficient to prevent knowing "delivery" of a study to a pesticide producer by either transferring the data directly or through publication. Thus, verbatim copies of a study should not be transferred without an assurance that the transferee is not a pesticide producer and publication should generally be limited to no more than two or more consecutive pages, except for summaries, conclusions, charts, tables, or graphs. The recipient of the data is also required to take appropriate steps to safeguard the data, including maintaining the data in a locked office when unoccupied or other secure facility.

STATEMENT OF NANCY DRABBLE, DIRECTOR, PUBLIC CITIZEN'S CONGRESS WATCH AND ALBERT H. MEYERHOFF, SENIOR STAFF ATTORNEY, NATURAL RESOURCES DEFENSE COUNCIL ON BEHALF OF CAMPAIGN FOR PESTICIDE REFORM

My name is Al Meyerhoff. I am a Senior Attorney with the Natural Resources Defense Council, Inc.[1] With me is Nancy Drabble, Director of Public Citizen's Congress Watch.[2] As the principal negotiators of the agreement with NACA, we appreciate the opportunity to testify on behalf of the Campaign for Pesticide Reform at these important Senate Agriculture Subcommittee hearings on necessary amendments to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

On March 20, 1986, the Chairman of this Subcommittee, Senator Richard Lugar, the ranking minority member, Senator Patrick Leahy, and Senator William Proxmire jointly introduced bipartisan legislation containing a host of amendments intended to strengthen FIFRA -- the principal federal pesticide statute in the United States. This legislation, S. 2215, reflects a carefully negotiated compromise following more than one year of negotiations between representatives of the Campaign for Pesticide Reform and the National Agricultural Chemicals Association. The bill has the full support, therefore, of more than forty environmental, labor and consumer organizations, including the Natural Resources Defense Council, Public Citizen, the AFL-CIO, Sierra Club, National Wildlife Federation, Consumer Federation of America, Consumers Union, American Public Health Association and others, and the more than ninety member companies of the National Agricultural Chemicals Association (NACA), including such pesticide producers as Ciba-Geigy, Shell, Eli Lilly, DuPont, Monsanto, and Union Carbide. To obtain such mutual support by the environmental community and chemical industry for broadbased legislation intended to overhaul a seriously-flawed pesticide law is both unprecedented and long overdue. As EPA Assistant Administrator Jack Moore has noted: "It is a momentous day when you have groups that have warred with each other for years agree to focus on what might be done."[3] Introduction of this bill thus marks an important step forward in bringing order to the regulation of pesticide chemicals in years to come. It also represents a test of good faith by all concerned. This agreement has already garnered widespread editorial support from all regions of the country and has generated extensive media coverage (attached at Appendix I).

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[1] NRDC is an environmental advocacy organization of lawyers and scientists with over 55,000 members.

[2] Public Citizen is a nationwide consumer organization, founded by Ralph Nader, which is supported by 100,000 members.

While no panacea, this legislation, if enacted, will result in a major improvement of a statutory scheme that now, most would agree, seriously fails to protect human health or the environment. An unbroken litany of Senate and House committee reports, investigations by the General Accounting Office, studies by the National Academy of Sciences and others, have consistently concluded that the current law has failed and failed badly.[4] This reform legislation will remedy many of the flaws in the current statute. It will require full health and safety testing of the roughly 2.7 billion pounds of pesticide chemicals added to the environment each year, add new resources at EPA to complete this "reregistration" process through imposition of an industry reregistration fee, give EPA new authority to cancel pesticides registered with invalid or fraudulent studies, require much-improved regulation of pesticide "inert" ingredients, and substantially streamline cumbersome EPA "special review" and cancellation procedures that have plagued the program and caused intolerable delays in removing known "bad actor" chemicals from the marketplace. Further, the bill will substantially tighten restrictions on chemicals sold abroad by providing effective notice to foreign countries of the environmental hazards of pesticides whose use in the United States has been banned, restricted, voluntarily withdrawn, or that were never registered for sale. The bill will also ensure a safer food supply by effectively prohibiting importation of food products containing residues of such banned or unregistered pesticides with certain limited exceptions.

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[3] New York Times, March 11, 1986.

[4] See, e.g., Sixty-third Report by the Committee on Government Operations, "Problems Plague the Environmental Protection Agency's Pesticide Registration Activities," 98th Cong., 2nd Sess., (1984), p. 17-18. (Synar Report); Subcomm. on Oversight and Investigations of the House Comm. on Interstate and Foreign Commerce, "Cancer-Causing Chemicals in Food," 95th Cong., 2d Sess., at 18 (Comm. Print No. 95-67, December 1978) (concluding that "many pesticides which result in chemical residues in food and animal feed have never been tested for their potential to cause cancer, birth defects, and genetic mutations"); Subcomm. on Admin. Practice and Procedure, Senate Judiciary Comm., "The Environmental Protection Agency and the Regulation of Pesticides, 94th Cong., 2d Sess., at 23 (Comm. Print 1976); General Accounting Office, "Delays and Unresolved Issues Plague New Pesticide Protection Programs," at 19 (1980) (noting that "the public is exposed daily to many pesticides which are not supported by animal and environmental safety studies").

Moreover, for the first time, FIFRA will include a community right-to-know provision requiring chemical plants to make available to local citizens and public officials pertinent information on health hazards of pesticides being produced at such plants. And, in order to greatly improve the opportunity for public participation in the critical pesticide registration process, scientific health and safety studies on pesticides will be made available before, rather than after, chemicals go on the market.

This agreement reached between the environmental coalition and chemical industry thus represents a major breakthrough and offers Congress a unique opportunity to act. Similar ongoing negotiations with the American Farm Bureau and others to address needed reforms on how these toxic chemicals are used in the fields and American homes, and are equally important and require equal commitment to the overall goal of ensuring the safe use of pesticide chemicals. Likewise, critical efforts to reach agreement on proposed legislation addressing protection of the nation's groundwater continue and are of vital importance. We plan to conclude these discussions promptly. Nonetheless, introduction of S. 2215 marks a dramatic and unprecedented step in the right direction.

Before addressing these proposed changes in the current law, it is useful to briefly review the negotiation process between the environmental community and pesticide industry that resulted in this consensus legislation. As this Subcommittee is probably too well aware, for many years a stalemate has existed between the industry and consumer groups on needed amendments to FIFRA. Previous attempts during the past several years to enact remedial legislation have consistently been opposed by industry and agricultural interests. Likewise, industry-supported efforts to further weaken the current law in 1982, including proposals to preempt state pesticide regulatory authority and to curtail access to health and safety data failed, due in part to opposition of environmental and other citizens' groups. Last spring, comprehensive FIFRA reform legislation was introduced in the Senate by Senator William Proxmire , co-sponsored by Senators Patrick Leahy and Tom Hardin of this Subcommittee, with bipartisan support from Senators Stafford, Humphrey, Chaffee and others. (S. 1303) Similar legislation in the House was introduced by Congressman George Brown (H.R. 2580).

Starting at the end of February last year, several preliminary meetings took place between representatives of a coalition of environmental, consumer and labor organizations and of the National Agricultural Chemicals Association, to explore the possibility of achieving agreement on proposed FIFRA amendments for consideration by this Subcommittee. These negotiations between these historic protagonists progressed and, following dozens of often-difficult and time-consuming sessions, an "agreement in principle" emerged in September of last year, ratified by both sides to the negotiations. During the past six months, further protracted negotiations went forward and proved successful. Last month, the National Agricultural Chemicals Association joined with the Campaign for Pesticide Reform to propose specific legislation to strengthen FIFRA and improve control of the use of pesticides in the United States and abroad. It is rare for such traditional opponents to agree on anything, let alone a major piece of environmental legislation.

Recognizing that the registration and safe use of pesticides is of interest to a variety of constituencies, CPR also has met periodically and discussed these and other proposed amendments with a variety of other groups, including the American Farm Bureau, the National Pest Control Association, the National Forest Products Association, the Chemical Specialities Manufacturers Association, the National Agricultural Aviation Association, the United Fresh Fruit and Vegetable Association, and other interested parties to obtain their views and where possible, work out differences. In addition, NACA circulated draft legislative provisions starting last October to nine trade associations and individually contacted twenty additional agricultural associations asking for comments. The Campaign for Pesticide Reform also made drafts public. Throughout the process, we have sought out the comments and suggestions of these trade associations and any other interested groups and have made every effort to take their concerns into account in drafting. We have probably set the world's record for number of meetings. However, no piece of legislation will satisfy everyone, and some organizations may not be interested in a compromise approach to FIFRA.

Also, negotiations have gone forward since last March with pesticide user groups, including the Farm Bureau, seeking to reach agreement on specific amendments addressing such issues as improved training for pesticide applicators, clarifying EPA's responsibility for the protection of agricultural workers, the maintenance of adequate records when pesticides are applied, and similar "use" related issues. While some progress has been made on certain of those issues, these negotiations are ongoing and have not yet reached closure. In addition, CPR is continuing to discuss with both NACA and the Farm Bureau the vital issue of protecting groundwater from pesticide contamination. Substantial progress has been made in these negotiations, now in their final and critical stage. Finally, throughout this process, we have met regularly with Assistant Administrator Jack Moore and other officials at the Environmental Protection Agency to seek their views on these amendments and how they will affect the Agency. While there are differences that remain with EPA, these meetings have also been generally quite positive and have added to achieving the breakthrough with the pesticide industry resulting in this agreement.

Obviously, obstacles remain. There are those that will oppose this legislation, who prefer business as usual or even to weaken the current law. As the legislative process begins, some who did not want to negotiate will advocate weakening amendments. While necessary adjustments can be made, we hope the Committee will resist attempts to undermine this compromise, since this legislation is a delicate balance which involved hard choices for everyone. Finding agreement on a series of FIFRA amendments supported both by the National Agricultural Chemicals Association and the environmental, consumer and labor community is no small achievement and presents an unprecedented opportunity to finally reauthorize FIFRA and strengthen a statute badly in need of reform.

I.

AN OVERVIEW OF S. 2215 FILLING THE DATA GAPS

Most would agree that the fundamental deficiency in the current regulatory scheme for pesticides is the absence of valid scientific data addressing the health hazards posed by the 2.5 billion pounds of pesticides used annually in American agriculture and American homes. Absent adequate studies on whether exposure to these chemicals will result in cancer, birth defects, genetic mutations, nerve damage or other acute or chronic health hazards, we are regulating out of ignorance. Without this basic information, efforts to effectively protect workers, consumers, the food supply or drinking water are doomed to failure. Since most pesticides in use today were registered before current testing requirements were adopted, what has charitably been called a "data gap" has been the reality of pesticide regulation in the United States for decades.

This glaring deficiency in pesticide regulation was recognized in 1972 when Congress first mandated that all pesticides be "reregistered" in light of contemporary standards. In the fourteen years since Congress acted, EPA can now give an assurance of safety for only sixteen of the more than 600 pesticide active ingredients on the market. For the vast majority of pesticides widely used in the United States, "data bases are woefully inadequate and [moreover] the existing data have not been evaluated by current standards." 5/ Thus, a report from the National Academy of Sciences in 1984 found that the pesticide industry had provided sufficient health and safety data for complete health hazard assessments on only ten percent of pesticides now in use. An earlier House Agriculture Subcommittee staff report found that 85 percent of the federally-registered pesticides lacked adequate data to assess their ability to cause cancer; roughly two-thirds lacked such data to assess teratogenicity, and 93 percent lacked adequate data to assess mutagenicity.

Currently EPA is undertaking reregistration through it registration standards program. A recent report by the Natural Resources Defense Council, evaluating the adequacy of EPA's registration standards program, revealed that the reregistration process is even more inadequate than previously known. By the end of FY 1985, EPA had issued 117 registration standards, but this number belies EPA's actual progress towards the original goal of reregistration. To date, only 16 pesticides have been reregistered. Fourteen years after the original Congressional mandate, EPA still has not issued final regulatory procedures for reregistration. Furthermore, EPA has stated that it would reregister a pesticide prior

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5/ Statement of Assistant Administrator John A. Moore, EPA before DORFA Subcommittee, House Agriculture Committee, April 18, 1985, p. 2.

to the submission and evaluation of required health and safety data.[6]

S. 2215 establishes a specific schedule for completion of reregistration of pesticides within seven years. Shortly following enactment of this legislation, EPA will be required to establish priority lists of pesticides for reregistration based on certain criteria and published in the Federal Register.[7] Within two years of enactment, the Agency will further be required to fully evaluate existing data on file by examining relevant protocols, documentation of the conduct and analysis of the study and results of the study and then identify "data gaps" both for non-existent studies and for studies that do not meet modern testing requirements. The Agency will then issue notices to registrants to fill such "outstanding data requirements" within specific deadlines, not to exceed four years. Deadlines shorter than four years will be established for studies completed more quickly (i.e., studies that do not require longterm feeding of laboratory animals), tracking EPA's current practice. Pesticide active ingredients will be dropped from reregistration lists where registrants voluntarily request cancellation of the product rather than conduct the necessary testing. Failure to submit data within such deadlines will result in mandatory suspension of a pesticide's registration.

Following receipt of a complete data base for a pesticide active ingredient, EPA will then have one year to throroughly examine the data for the pesticide and

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6/ Unfortunately the issuance of a registration standard is in no way equivalent to a reregistration of the pesticide. By the end of FY 1985, EPA had issued 117 Registration Standards. But for only eight of these did EPA have complete health and safety data submitted at the time the standards were issued. Indeed, for twenty-one pesticides, standards were issued with no chronic health effects data whatsoever. In short, issuance of a Registration Standard no longer means that a pesticide has been reregistered. EPA's current reregistration program is reregistration by slight of hand.

7/ In establishing an order of priorities for reregistration, the Administrator shall give the highest priority to pesticides that are in major use on or in food, may result in residues of toxicological concern in groundwater, have the most significant data gaps or are used on crops where worker exposure is most likely to occur.

complete reregistration by determining whether the pesticide fulfills the requirements of FIFRA Sec. 3(c)(5). Such reregistration will not bar the Agency from subsequently requesting additional data or taking any other appropriate regulatory steps, including initiation of a special review or cancellation of the active ingredient involved.

Finally, the lynchpin for the reregistration amendment is the imposition of a $150,000 reregistration fee on active ingredients to provide additional resources to EPA to ensure successful completion of the reregistration process. This fee is divided into two parts. A fee of $50,000 initially is assessed on each pesticide active ingredient when EPA issues its notification of an outstanding data requirement to provide funds for EPA to identify the data gaps. An additional fee of $100,000 is assessed when the registrant submits the required data to provide resources for EPA to evaluate the data. Lesser fees may be assessed for registrations of active ingredients not used on food or feed, stemming from the fact that it takes less data to reregister such pesticides. Formulators are exempted from paying any fee and reregistration fees are apportioned among pesticide active ingredient registrants.

These amendments, modeled on the California Birth Defect Prevention Act of 1984 (SB 950), which garnered broad bipartisan support in the California Legislature and was signed into law by Governor George Deukmejian, would finally bring some certainty to the regulation of pesticides. Farmers, users, consumers, workers and the public as a whole all benefit from ensuring that products to which they are regularly exposed have been adequately tested and do not result in acute or chronic health effects to themselves or their families.

MINOR USES

Some have raised the question whether S. 2215 will harm the registration or reregistration of minor uses. This issue is a red herring for several reasons:

1. EPA already gives minor use registrations special treatment in five ways. First, under FIFRA section 3(c)(2)A, the agency must make data requirements for minor uses "commensurate with the anticipated extent of use, pattern of use, and the level and degree of potential exposure of man and the environment to the pesticide." In 1979, EPA published a policy statement in the Federal Register to implement the 1978 amendments. 44 Fed. Reg. 12097 (March 5, 1979). In 1984 EPA issued final data

requirements for pesticide registration that contain considerable flexibility on the date required for individual uses. One section of the regulations, 40 C.F.R. Part 158.60, specifically states that EPA will appropriately adjust data requirements concerning minor uses. Second, registrants can petition for waivers from data requirements and EPA will take into account the minor use factors in section 3(c)(2)(A) in its decision on the waiver. Third, EPA, under section 2(e)(e), permits the use of the pesticide on an unlabeled pest as long as the crop appears on the label. Fourth, EPA has implemented a crop grouping scheme, under 40 C.F.R. Part 180.34(f), that permits the establishment of tolerances for a group of crops based on residue data for certain crops that are representative of the group. Once a crop group tolerance is set, the tolerance level applies to all raw agricultural commodities in the group. Fifth, in FY85, EPA issued a CORT (carcinogenicity, oncogenicity, reproductive effects, and teratology) Data Call-In for all food and feed uses. As a result, the process of abandoning registration of economically marginal pesticides in face of considerable toxicology testing costs is already underway without the reregistration amendments in S. 2215. Minor uses have not been harmed.

2. The S. 2215 reregistration fees are a negligible consideration in a manufacturer's decision to comply with reregistration testing requirements. One chronic (two-year animal) toxicology study can cost $500,000, and total testing costs can run in the millions, depending on the extent of the data gaps. The reregistration fees will be insignificant compared to the likely requirements for several chronic studies. The decision to maintain a chemical's registration by conducting the studies will be based on the anticipated total future economic return of the chemical.

3. The fee is particularly minor since it will be divided among all the registrants of an active ingredient (and there may be several) and it only applies to the active ingredient, not all the formulations that result from that active ingredient. For example, one active ingredient might be registered for 15 uses and be used in 100 formulations, but there would be only one reregistration fee.

4. EPA has recently removed more barriers to minor use registration. A new Agency policy has just been issued that will aid tolerance setting for minor uses. 51 Fed. Reg. 11341 (April 2, 1986). Under the new policy, EPA will consider granting tolerances for minor use crops with regional (instead of nationwide) residue data, waive

tolerance petition fees ($44,000) for minor use crops, and give priority handling to minor use tolerance petitions.

S. 2215 would not affect either EPA's existing or new policy which encourage minor uses.

5. The S. 2215 reregistration amendment would require an accelerated effort to obtain full health and safety testing on all pesticides. Fees of $150,000 per food or feed use pesticide active ingredient will be charged to finance the program. (Reduced fees are authorized for nonfood or feed use pesticides.) The fees are divided among all registrants for all uses of the active ingredient.

This fee will not deter the reregistration of minor uses. EPA has said there are no active ingredients registered only for minor crops. Therefore, the decision whether to proceed with reregistration will be based on the profitability of the major and minor uses taken together. In addition, manufacturers of food use active ingredients have already decided whether to replace chronic health effects studies and minor uses have not suffered.

6. Some have argued that the tightening of conditional registrations will hurt minor uses. This is not true. Under S. 2215, conditional registration of a pesticide would be permitted if all data required solely for the additional use have been submitted, the conditional registration would not materially increase the risk of any unreasonable adverse effect, and the additional use is in the public interest. However, no conditional registration would be granted for a pesticide that is being scrutinized in Special Review because of risks from dietary exposure. Further, no conditional registration would be granted for uses other than minor uses if chronic toxicity (oncogenicity, reproductive effects, and mutagenicity), neurotoxicity or teratogenicity data are required but have not been submitted.

Thus, this amendment specifically exempts minor uses from its prohibition of new conditional registrations when key toxicology data is missing. Conditional registrations for major or minor uses would not be granted when a chemical is suspected of posing a dietary hazard and has been placed in Special Review. If a chemical is potentially hazardous and is receiving Special Review scrutiny, no new uses should be added at that time. It is already EPA's policy not to grant any conditional registration unless all data required to support the additional use (most typically residue chemistry) have been submitted.

II.
RESTRICTION OF CONDITIONAL REGISTRATIONS

In the past, the "data gap" problem has actually been exacerbated through a provision in FIFRA authorizing "conditional" registrations of new active ingredients or new uses of already registered pesticides without full health and safety data. Intended to permit rapid marketing of safer, if not fully tested, active ingredients, the conditional registration system has offered a serious loophole which has been abused in the past. Thus, of the ten to fifteen new pesticide active ingredients registered for use each year, EPA grants conditional registrations for roughly half. More and more new chemicals are permitted on the market without required data.

Under the S. 2215, such conditional registrations would be severely restricted. EPA would be prohibited from granting a conditional registration for a new use or a new active ingredient where data concerning chronic toxicity (carcinogenicity, reproductive effects and mutagenicity), neurotoxicity or teratogenicity are required for registration but have not been submitted. Conditional registrations will be refined further by amendments to FIFRA Sec. 3, stating that such registrations must not, in any event, materially increase the risk of any unreasonable adverse effect on the environment and that any new use is in the public interest (i.e., is intended to replace the use of a different active ingredient that poses greater hazards to humans or the environment).

III.

CANCELLATION OF PESTICIDE REGISTRATIONS BASED ON FALSE OR INVALID DATA

During the 1970s, it was learned that the now-defunct firm of Industrial BioTest Laboratories (IBT) had systematically submitted large numbers of falsified research studies and outright fraudulent data over an extended period of time. IBT was the locus for one of the greatest scientific scandals in recent decades. First discovered by chance by a lone FDA scientist in 1976, fraud and shoddy research practices were found by federal investigators to be pervasive. This one lab was estimated to be responsible for between 35 and 40 percent of toxicological tests in the country. The registrations of over 200 pesticides were based, to some degree, on IBT data. More than 90 percent of the studies conducted by IBT were subsequently determined by EPA to have been invalid. EPA officials have testified before the Congress that, in circumstances like IBT, once a pesticide is registered, they lack the legal authority to cancel or suspend such registration even where the data is later determined to be false, inaccurate or fabricated. In a Catch 22 analysis, EPA says that such cancellation may occur only where there is evidence of adverse effect on the environment which cannot, by definition, be shown with invalid studies.

The Lugar amendments will specifically address this issue. First, EPA will be required to immediately issue a notice of intent to suspend and cancel the registration of any pesticide registered with IBT data where such data is material to the registration and has not been replaced. In addition, in the future, if the Administrator determines that invalid data have been submitted by a registrant in support of a registration, EPA may either require submission of valid replacement studies or issue a notice of intent to cancel the pesticide's registration where necessary in the public interest, taking into account the scope of the invalid data and need to use the data to determine whether the pesticide may cause unreasonable adverse effects on the environment. Willful submission of invalid data will result in mandatory cancellation. Finally, the bill establishes an expedited 75-day hearing procedure to contest such cancellations.

IV.

IMPROVED REGULATION OF INERT INGREDIENTS

Recently, the Environmental Protection Agency identified approximately one hundred pesticide "inert" ingredients believed or suspected of being of "toxicological concern" to the Agency. In recent testimony before this Subcommittee, Assistant Administrator Jack Moore acknowledged that the Agency's record in regulating inert ingredients was seriously flawed. Under current law, the Administrator is not required to evaluate the safety of so-called "inert" ingredients and, while classified as inerts, many such ingredients may, in their own right, present serious threats to public health and the environment. For example, benzene, chloroform, formaldehyde, the glycol ethers, epichlorohydrin, vinyl chloride, hydrozene, and xylene have all been used as pesticide inert ingredients as have various active ingredients from other formulations, including such known health hazards as pentachlorophenol. Yet current law does not even provide for identification of such hazardous inerts on the labels of products to which the public is frequently exposed. (Thus, it was recently learned that the widely-used pesticide dicofol, a home use and agricultural pesticide that has also been found in groundwater, contained the banned pesticide DDT as an inert ingredient and contaminant.)

This bill would establish clear legislative authority to regulate inerts and create an appropriate regulatory regime to accomplish that result. It mandates EPA to develop a priority list, initially of fifty inert ingredients and subsequently raised to no more than 75, to be targeted for regulation, including the requirement of necessary health and safety tests to fill the inert ingredient "data gap," the companion of the active ingredient data gap discussed previously. Such inerts become candidates for listing when they are already known to be hazardous, are structurally similar to known hazards, or when an absence of adequate health and safety data exists and there is widespread use or exposure.

Once an inert is listed, EPA is required to develop and publish within one year a plan of what toxicity studies must be conducted and the deadlines for submission of such studies, not to exceed four years. When data is received by EPA it must be reviewed, and appropriate regulatory action must be taken by EPA within one year of data receipt. It is anticipated that this list will be dynamic with inerts coming on and off the list in accordance with the criteria. Once EPA decides to require testing, such inerts must be identified on a pesticide product label. Inerts will be removed from the priority list following the initiation of appropriate regulatory action by the Administrator, such as initiation of special review of the pesticide or action under Sec. 6 or the receipt and evaluation by the Administrator of all required health and safety data. Health and safety data generated on such inerts will be available for public review pursuant to Sec. 10 of FIFRA. Finally, this amendment provides for appropriate data development cost allocation and encourages substitution of hazardous inerts with other inert ingredients that do not pose the same or similar concerns of adverse effects on health or the environment.

V.

PUBLIC ACCESS TO PESTICIDE HEALTH AND SAFETY DATA PRIOR TO REGISTRATION

Under current law, the general public is provided an opportunity to comment on proposed pesticide registration decisions by EPA before a new chemical is put on the market. However, effective public comment is severely undermined since FIFRA provides that health and safety data is available thirty days *after* a regulatory decision has been made. Public participation in such circumstances becomes little more than symbolic. And, as the experiences with a host of pesticides such as EDB, heptachlor, chlordane and DBCP make clear, once a pesticide is licensed or registered, removing it from the market is a lengthy, expensive and Sisyphus-like process.

Under the S. 2215, full access to pesticide health, safety, and environmental data will be provided for all new active ingredients and initial food uses of existing registered pesticides. The amendments authorize access shortly following EPA's publication of receipt of an application for federal registration in the *Federal Register*. Once permission to examine the data is granted, sixty days will be provided for public comment. Data will be made available both in offices of EPA and at authorized state agencies, upon submission of an affirmation by the requester that he or she is not acting for a pesticide company and will not intentionally or recklessly violate other restrictions in the Act that protect confidentiality. Comments may reasonably quote and discuss the data and may be exchanged for peer review but will not be made public until after a registration decision has been made and then in conformity with the Sec. 10 confidentiality provisions of FIFRA. Finally, substantial penalties are imposed for wrongful use of the data for commercial purposes. In an historically controversial area, this provision of the bill was carefully crafted to substantially increase rights of the public to scrutinize industry-generated health and safety studies prior to registration while at the same time including necessary safeguards to prevent unauthorized use of such data for a commercial purpose.

VI.

ESTABLISHMENT OF A PUBLIC RIGHT TO KNOW

Under this bill, FIFRA for the first time will include a community right-to-know provision requiring the chemical industry to make fact sheets with pertinent information on the health hazards of pesticides available to citizens residing near pesticide plants and to other fire, police and health officials. In light of recent events both in Bhopal and here in the United States, this provision represents an important step forward in establishing an overall right to know for local communities. The proposed amendments will direct pesticide registrants to develop and submit to EPA a summary of health and safety data supporting their registered active ingredients as well as inert ingredients listed on EPA's priority list under a separate provision of the bill. These fact sheets are intended to be similar to those required under the OSHA Hazard Communication Standard known as Material Safety Data Sheets. The fact sheets will be kept current by registrants and made available to the public on request. Further, the Administrator may require amendments to the fact sheets in order to ensure that they contain accurate and clear information for the public. In a companion measure, S. 2215 requires registrants to submit with their registrations a list of locations throughout the United States where pesticide active ingredients are being produced. An amendment to the confidentiality provisions of FIFRA will make clear that the public may have access to the identity of these locations in order to facilitate access to pertinent health and safety information.

VII.

REFORM OF THE PESTICIDE REGULATORY PROCESS

In a 1980 General Accounting Office report, referring to its previous report in 1975, the GAO concluded that:

> ... Our 1975 report to the Congress stated that the public is exposed daily to many pesticides which are not supported by animal and environmental safety studies. The situation has not improved. The Assistant Administrator for Pesticides and Toxic Substances stated that not much difference exists between the present condition of EPA's test data files and those that existed at the time of our 1975 report. "Delays and Unresolved Issues Plague New Pesticide Protection Programs," February 15, 1980, at p. 19.

In the next few weeks, the GAO will complete a new investigation of EPA's pesticide regulatory process. It will almost certainly find that, once again, little has changed since its 1975 and 1980 reports. Budget cuts in the pesticide program combined with a short-lived but harmful system of EPA-industry "decision conferences" brought EPA's pesticide regulatory system to a virtual halt for nearly three years. Following litigation by NRDC and others, that system has now been eliminated. Recently-promulgated regulations will, in the future, ensure that pesticide regulatory decisions are made openly and independently by the Agency. Only recently has the EPA pesticide office begun to show some semblance of vitality.

Nonetheless, as numerous examples establish, the problems at EPA are systemic. The principal regulatory mechanism EPA established for expedited action for pesticides that are potentially hazardous is known as "Special Review" or the Rebuttable Presumption Against Registration (RPAR). When first established in 1975, Special Review was intended to be a kind of "worst first" system to focus Agency resources on a particularly troublesome chemical, with the entire procedure designed to take no more than 300 days. In fact, such special reviews drag on interminably. Examples of this process are now legendary. The well-publicized case of EDB still perhaps is the most illustrative.

While EDB was found to be a probable human carcingoen by the National Cancer Institute in 1974, RPAR was not initiated until 1977. The product was not removed from the market until 1984, seven years later. Other examples abound. Captan was placed into Special Review in 1980 due to evidence of carcinogenicity, teratogenicity and mutagenicity; a final regulatory decision on Captan is anticipated some time after April 1987. The highly-toxic chemical pentachlorophenol was placed into RPAR or Special Review in 1978 after being linked to birth defects and due to the carcinogenicity of its contaminant, HxCDD, a form of dioxin. Studies linked penta with birth defects as early as 1974. A "final" decision was issued in July, 1984 but that is now tied up in administrative appeals. Thus, eight years after the penta RPAR was initiated, the chemical remains on the market, without restriction, used in childrens' playgrounds, as a general wood preservant, and sold over the counter to an unknowing public.

The EBDCs, a family of six different chemicals that are among the most widely-used fungicides in the United States, are carcinogenic as is their metabolite, ethylene thiourea (ETU). Cancer risks on the EBDCs and ETU run as high as one in 100 for applicators, with dietary exposure in the four in 1000 range. The EBDCs were placed into RPAR in 1977 -- nine years ago. A preliminary regulatory decision on the EBDCs is anticipated by EPA by December of this year.

The most recent, and, in some ways, textbook, example of regulatory inertia at EPA involves the widely used plant growth regulator, daminozide or Alar. Daminozide is used to enhance redness, delay fruit maturity and extend storage life for apples and certain other crops.

A series of studies in the early 1970s reveal that daminozide and UDMH are potent animal carcinogens. After first waiting several years, EPA in 1980 privately notified the pesticide registrant, Uniroyal, of its "risk concerns" about daminozide. However, no Special Review was initiated for four years, and during this period a series of closed-door meetings with Uniroyal occurred. At no time did Uniroyal initiate any of its own carcinogenicity tests on its product, even though daminozide had been on the market since 1968. Finally, in September, 1985, EPA issued a proposed decision on daminozide cancelling its food uses because of an unreasonable health risk to the public. The Agency then reversed itself, however, after its own Science Advisory Panel found flaws in the daminozide database and sharply criticized both EPA and Uniroyal for not generating more complete studies on this widely-used chemical. In actuality, the flaws on the data, involving among other things, a smaller-than-usual number of test animals, would understate the carcinogenicity of daminozide and the resultant threat to public health. Nonetheless, this chemical will now remain on the market, and in the American food supply, for years to come while Uniroyal finally conducts necessary chronic testing.

Enactment of S. 2215 will go a long way to prevent the daminozides of the future. It will streamline the EPA regulatory process in several respects. First, EPA will be required to initiate Special Reviews upon receipt of evidence demonstrating that Special Review triggers have been exceeded. The criteria for initiating Special Reviews will be established on the basis of levels of risk, and such Special Reviews may not be delayed due to the unavailability of exposure data. Once a notice of a review is formally initiated, the amendments provide for full public participation and a specific schedule for completion of the review. Key elements of the schedule call for a 90-day public response to EPA's notice of Special Review, 90-day EPA review of public comments and issuance of a proposed decision, 30-day Science Advisory Panel review, and a 60-day deadline thereafter for final EPA decision. The overall time for completion of the Special Review is one year. This deadline may be extended for one year in exceptional circumstances where it is necessary to obtain additional data pivotal to an accurate determination of the risks involved. Such an extension will be available only where the Administrator acted to obtain such additional data at the time the review was initiated. In short, these reforms, while providing sufficient time to make an informed decision, will ensure that the abuses of the past are not repeated by preventing the inordinate delays that have plagued the EPA regulatory process and undermined public confidence in industry, EPA and government in general.

Similarly, the S. 2215 will address unacceptable delays that occur in the cancellation hearing process as well. Under current law, even after completion of a Special Review, lengthy and time-consuming cancellation hearings are also provided before a suspect pesticide can be restricted or removed from the market. Under S. 2215, EPA may regulate a pesticide through changes in its labeling through informal rulemaking unless those changes are equivalent to a cancellation of use, render the product unmarketable, or otherwise have a major economic impact on the product. Further, steps that unnecessarily delay cancellation, such as referral of matters to the National Academy of Sciences, would be eliminated. Finally, any cancellation following a Special Review must be completed within six months unless that time limit is extended in exceptional circumstances, and then for no more than 180 days. Similarly, cancellation hearings occurring absent a Special Review must be completed within one year.

VIII.

STRENGTHENING PESTICIDE EXPORT PROTECTIONS

Under current law, pesticides that are cancelled, voluntarily withdrawn from the market, restricted or not registered in the United States, may nonetheless continue to be sold abroad. While not altering that fact, the Lugar-Leahy-Proxmire bill would make significant improvements in protections provided to countries importing such hazardous chemicals by ensuring greater knowledge of the risks involved. First, the amendments would expand current notice requirements by requiring exporters to provide the foreign government with information about the pesticides 30 days before export. The notice and acknowledgement of receipt must be delivered to EPA and made available to the public. Such notices will identify the exporter, the foreign purchaser, the appropriate foreign regulatory office and will include a clear statement of the reason why the product cannot legally be sold in the United States or is in a restricted use. EPA must annually provide similar notices to foreign governments.

Second, this legislation will mandate that exported pesticides which are substantially similar in composition and use to pesticides registered in the United States contain labels providing the same health, safety and hazard precautions as the U.S. products unless to do so would violate the law of the importing country. Such labels are to be written in an appropriate language.

Finally, this legislation will require EPA to revoke or amend food tolerances when a pesticide registration has been cancelled, suspended, denied or voluntarily withdrawn unless such action was due solely to environmental rather than human health concerns. The action on the tolerance may take into account consumption of food in commerce, use of existing stocks, and unavoidable environmental contamination. Finally, this amendment encourages EPA to assist foreign governments in establishing comprehensive pesticide programs.

IX.
OTHER AMENDMENTS

In addition to the foregoing, this legislation contains a series of other amendments intended to strengthen FIFRA. For example, the proposed amendments require that no employer may retaliate against, discharge or otherwise discriminate against any employee because the employee or a person acting at the request of the employee has initiated a proceeding under FIFRA or testified or participated in such a proceeding. This provision is to be implemented in a manner consistent with a similar section in the Toxic Substances Control Act.

The amendments also will, for the first time, permit EPA to disclose to appropriate state agencies, any data or information acquired under FIFRA so long as the state ensures that registrants will be provided adequate protections for confidential information. This provision will not only improve the effectiveness of state programs but will also facilitate access to health and safety data at state agencies throughout the country. Finally, the bill includes amendments that will authorize EPA to inspect relevant parts of laboratories, books, records and other materials in order to avoid a repetition of the experiences with fraudulent research and shoddy laboratory practices that led to the Industrial BioTest scandal.

CONCLUSION

In the small California town of McFarland, a community of 6400 people, it was learned recently that eleven children have contracted nine different kinds of cancer between 1981 and 1984. Two have already died. Three lived on the same street. The cancers included brain tumors, leukemia and lymphoma, the last responsible for the death of a four-year-old. Eighty miles to the north, in the tiny Fresno County city of Fowler, three children have developed leukemia during the same period. In addition, unusually high numbers of miscarriages, fetal deaths and low birth rates have also been reported in both communities. Just why cancer is striking the children of McFarland and Fowler remains a mystery, as is so often the case, but toxic chemicals from agriculture found in the drinking water supply are the principal suspects. Residues of the pesticides DCP and DBCP have been found in wells as have various nitrates and other chemicals. These events follow a 1982 epidemiological study that showed a significant increase in fatalities from stomach cancers and leukemia in this part of California's vast San Joaquin Valley.

S. 2215 presents an opportunity for us to avoid the McFarlands of the future. Increased public participation, comprehensive testing, an enhanced public right to know, expedited EPA regulatory procedures and a host of other reforms contained in this bill deserve enactment. We owe it to the children of McFarland.

Thank you for your attention. We will be glad to answer any questions you might have.

Committee Note: Articles from newspapers and magazines were submitted for the Hearing Record as Appendex I. Due to the cost of reproduction, the Committee will not reproduce the articles, but copies will be retained in Committee files.

The articles are as follows:

Good Bargain on Pesticides, March 13, 1986, The Washington Post
Good News on Pesticides, March 17, 1986, Los Angeles Times
Control Pests and Monopoly, Too, March 13, 1986, The New York Times
New pesticide bill: good compromise, March 24, 1986, Great Falls (MT) Tribune
The pesticide risk, March 12, 1986, San Jose Mercury News
Agreeing on pesticides, March 14, 1986, The Fresno Bee
Policing Pesticides, March 17, 1986, The Tampa Tribune
A cheer for a truce in pesticide war, March 20, 1986, Daytona Beach (FL) News
Finally, a promise of action on pesticides, March 17, 1986, Minneapolis Star and Tribune
Pesticides on the dinner table--Bill aimed to control chemical use, March 26, 1986, Columbia Missourian
Miracle on 15th Street", Farm Chemicals
Getting control of pesticides, March 22, 1986, The Philadelphia Inquirer
Put the lid on pesticides, March 15, 1986, Dallas Times Herald
All Hail the Pesticidal Amnesty, March 28, 1986, The New York Times
Antagonists Agree on Pesticide Law Reform, April 4, 1986, Science
Environmentalists, Firms Agree on Bills, March 11, 1986, The Journal of Commerce
Measure Would Speed Up Pesticide Tests, March 11, 1986, Los Angeles Times
Agreement Reached on Pesticide Bill Details, March 11, 1986, The New York Times
Pesticide Control Finally Tops the EPA's List of Most Pressing Problems, March 6, 1986, New York Times

STATEMENT OF MARK A. MASLYN, ASSISTANT DIRECTOR, NATIONAL AFFAIRS DIVISION, AMERICAN FARM BUREAU FEDERATION

We appreciate the opportunity to be here today to share with you Farm Bureau's comments and suggestions on various proposals to amend FIFRA. I am the assistant director of the National Affairs Division for the American Farm Bureau. The American Farm Bureau Federation is a general farm organization in 49 States and Puerto Rico. Membership of Farm Bureau includes producers of nearly every crop grown and harvested commercially in the United States.

Farm Bureau earnestly hopes that Congress will be able to pass a multi-year FIFRA reauthorization in 1986. We recognize the need for some changes in FIFRA and have participated in efforts to resolve hearings. Like the National Agricultural Chemicals Association, Farm Bureau and other representatives of the pesticide user community have been meeting with the Coalition for Pesticide Reform for much of the past year. We view this effort as a constructive attempt to augment the normal legislative process and increase the likelihood of a multi-year FIFRA package in 1986. It is my sincere hope that these negotiations will continue and that an agreement can be reached in several areas within the next few weeks.

In our review of S. 2215, most of the provisions are acceptable and will have little impact on agricultural producers. However, there are several provisions that will have a detrimental effect on agriculture, either by increasing the cost of the pesticide product, or in some way affecting the availability of these products to farmers and ranchers. Of particular concern are the effects these provisions would have on producers of so-called "minor crops".

Section 301, titled reregistration and revenues, sets forth an ambitious schedule for the agency to complete the reregistration of existing pesticide products. As users who are in the first line of exposure, we support the objective of bringing all products up-to-date, thus ensuring their safety and effectiveness to farmers and ranchers. We believe, however, that the timetable established in S. 2215 may place unreasonable expectations on the agency and suggest that it be drawn out over a longer period of time.

We are also concerned over the establishment of reregistration fees. These fees, totaling $150,000 per active ingredient, are apparently intended for use by the agency to hire additional staff to comply with the expedited reregistration process. These fees, which will total $70 million, will undoubtedly be passed along, driving up production costs to farmers and ranchers and further erode net farm income. In addition, they set a potentially onerous precedent of user fees for agricultural chemicals. Our concern, however, extends beyond the prospect of higher priced products. We believe that the combined effects of an expedited and rigid reregistration schedule, and the additional requirement of reregistration fees will hasten the removal of many products from the marketplace, leaving farmers without adequate means to protect their crop investments. This is of particular concern to growers of minor food and feed crops as well as growers of nursery and ornamental stock.

This concern for specialty and minor crop producers also extends to the changes proposed to the conditional registration provisions. The current language, which allows the Administrator to determine "that the applicant has submitted satisfactory data pertaining to proposed additional use", should be retained and the proposed language "all additional data that are required" be omitted. Flexibility is required in these circumstances and is important in imposing requirements and timetables on minor use pesticides and may in fact be the determining factor on whether or not a low volume pesticide use is omitted.

From the standpoint of farmers and ranchers, one of the most pressing needs in FIFRA is to afford a measure of protection from liability to individuals who conscientiously adhere to federally approved label directions, employ generally accepted farming practices, adhere to the recommendations of USDA extension service and demonstrate their level of proficiency through the training and certification programs. At the heart of liability protection is the question of fairness, but beyond that it just makes good sense from the environmental standpoint to provide that added incentive to farmers and ranchers who can demonstrate that they have used the product according to Federal label guidelines.

We strongly support the concept of public right-to-know and the language contained in this bill seems to be a reasonable solution to a growing concern of how to make pertinent information about chemical products available to the general public. These provisions would not only benefit the local community and emergency personnel but farmers and ranchers as well who are frequently called on to supply information about particular pesticide products.

Another area of concern to farmers and ranchers is with the issue of governmental authority to regulate pesticides. We believe that the amendments to FIFRA should clarify this issue and provide for the Federal and State preemption of local government authority to regulate pesticides.

Farm Bureau is also very much opposed to including in FIFRA any citizen suit provision or private right of action. Such a provision would in the very least result in the harassment of farmers through nuisance suits alleging violations in FIFRA in the course of normal farming practices. If there are enforcement problems, either with EPA or in the State contracted agencies, they ought to be dealt with directly to ensure that FIFRA is in fact an effective statute. However, permitting every individual to become a defacto enforcement officer is not the correct solution.

Finally, the issue of groundwater protection is a rapidly emerging issue which will undoubtedly be in the forefront of discussion for years to come. Farmers and ranchers who are served overwhelmingly by private wells in rural areas have much to be concerned with from the standpoint of both health and safety as well as potential restriction and limitations on land use practices. We recognize that the groundwater issue has to be addressed, but we are also concerned that from an agricultural standpoint it must be addressed in a practical and realistic manner. We support the idea of addressing groundwater in FIFRA and are working with the Coalition for Pesticide Reform and the National Agricultural Chemicals Association in an effort to develop a mutually acceptable proposal.

Mr. Chairman, let me restate our support for a FIFRA package this year and our intention to work with you and members of the committee to ensure that this product is both effective and fair to all interested parties. Thank you.

STATEMENT OF RON D. WHITE, REPRESENTING TEXAS DEPARTMENT OF AGRICULTURE

Mr. Chairman and members of the committee, my name is Ron White and I am here on behalf of the Texas Commissioner of Agriculture to tell you how we think this bill will make it easier for States to do their part of the pesticide regulation job and to answer any questions that you may have.

By way of background, I have been managing the regulatory program in Texas for the last 3 years. In addition, I am currently a member of an official advisory committee which EPA has organized to help write new worker protection standards. In Texas, we have made great strides in increasing worker safety and in improving our training and education programs. Yet much remains to be done and this bill will lay necessary groundwork for further progress by the States and EPA.

Introduction

I want to say very plainly that you have the opportunity to pass a bill which takes some significant steps forward. This opportunity should not be allowed to escape. This bill needs to be passed by both Houses and signed by the President. I want to state for the record that we support the agreed-upon provisions of the bill. Before I go any further, I want to thank the people who worked together and compromised some long-held positions to develop this bill. It could not have been easy. I know from personal experience that even your best friends may not understand why you did what you did. But I want publicly to say thanks to these folks for making some really important progress on issues that everyone finds vexing.

It is heartening to note that the New York Times and the Washington Post have put their weight behind the agreement, too. This bill has people's attention.

I will begin by commenting on the key provisions that the negotiators agree on. Following that, I want to suggest some approaches to two remaining issues.

Why we support the Bill

We support the bill because it accomplishes some very important things.

First and foremost it gets the reregistration of the old chemicals on a faster track. I really do not think there is anything more important than this. At present, we find a problem with a product--and some of these problems have been quite serious--and everything stops until we get the problem solved. What is needed is an orderly process that examines these products which are being used everyday and gets them properly categorized and either reregistered or off the market. Congress has repeatedly asked for this and its wishes have never been complied with. I am not blaming this administration nor the people who have testified at this hearing from EPA. The simple fact of reregistration is this: Congress asked that it be done by October 21, 1976 and you now find out that, at the current rate of progress, it will be early in the 21st Century before it gets done. Fundamentally it is a matter of resolve and resources. Congress has to show in this bill that it has the resolve and give the folks at EPA the resources. No matter who you are or how you look at this, the answer is the same: reregistration has to be done just as soon as humanly possible.

When I meet with farmers or consumers in Texas they all tell me that they believe that the pesticides they use have been tested and approved by EPA. When they find out that there are many products on the market which have not been tested, they are absolutely astonished. When they find out how long this situation has been allowed to go on, they get angry. I cannot blame them. Nor can I explain to them why it has happened.

A farmer has a right to expect that the pesticides that he and his workers are being exposed to are tested and that if he uses them according to instructions that he and his workers will not be put at undue risk. Unfortunately, the regulatory system is not living up to his expectations. Farmers do not want to end up with grain in their bins which has been treated with a pesticide that turns out to be a high risk carcinogen. The time to test pesticides is before they are used. Since in many cases we are already beyond that point, reregistration must have the highest possible priority. I do not think you would be asking too much to insist that this long-overdue work be done very promptly.

EPA and State enforcement agencies also need to have the testing done. Without such information EPA cannot design a sensible groundwater monitoring strategy. You simply cannot test everywhere for everything. You have to know which products are most likely to be a problem in which locations or which soil types, etc. Reregistration will yield data about the environmental fate of products which have long been in use. Some of this information will reveal the likely conditions under which these products will leach into the groundwater, bind up with the soil, [illegible] degrade into harmless elements. We know from our experience with arsenic, which has been found in a number of wells, that EPA does not know what it needs to know about the product. The EPA model does not predict that leaching will occur, yet it does. This is just one instance where insufficient information has been very costly. Had the data been available prior to use, alternatives could have been used or application rates or timing adjusted to prevent damage. In the case of arsenic, there really is no way to eliminate the contamination which we now have. The absence of information also prevents state enforcement agencies from being sure that they have their priorities straight. The priority setting mechanism is driven by complaints. Yet complaints arise mainly out of acute human health problems and herbicide damage to non-target plants. We cannot depend on complaints to tell us that there is a chronic health problem with a product. Cancer and other problems take a long time to develop and people cannot link cause and effect. Yet lab tests with animals will tell us where and when to provide protection to mixers, loaders, applicators, and workers who must come in contact with pesticide residues. To depend on complaints is simply to use people as indicator organisms, like the canaries of the miners. The States and EPA need the information the reregistration will yield so that they can do their basic regulatory work of protecting people and the environment.

The research priorities of the manufacturers have been distorted by the failure to test and reregister these products. They cannot guess any better than farmers which old, untested pesticide will be knocked off the market by some independent scientist's work. Therefore when EPA gets to the point of cancellation, they may be facing a situation in which the alternatives are about as bad as the product being cancelled--grain fumigants, for example. If manufacturers knew that EPA was serious about carrying out the reregistration program on a reasonable schedule, they would then know where to devote their research time.

An item related to the testing needed for reregistration is the testing needed for a conditional registration. I strongly support the provisions which would require the submission of specific chronic test results before a conditional registrations could be granted. There is a great deal of evidence that supports the idea that we need thorough testing before we use a pesticide. It is a wise principle and it should be applied to conditional registrations.

The second major accomplishment of this bill is that it gets serious about inert ingredients. This is an area that surely too little is known about. But, as those who have learned the right questions to ask have discovered, inert does not mean benign. In fact, some of the inert ingredients are more harmful to people than the active ingredients are. There is a whole lot we do not know about inerts and it is time to repair that deficiency.

Third, the community right to know provisions are important. People who live with these products are entitled to know some basic facts about them. It is time to stop being condescending to the people who are neighbors to these plants and the provisions of the bill are a major step in the right direction.

Fourth, the bill makes very clear to EPA and registrants that the States who, after all, enforce FIFRA are entitled to know the details of the pesticides. In case anyone thinks this provision is not needed, let me say that we have a data request that is still pending at EPA. In August it will be three years old. It is not easy to get some information from EPA; they are simply not willing to run the risk of sharing information with States as FIFRA is now written. This provision needs to be a part of any pesticide reform bill that gets passed.

Fifth, the provisions dealing with the importation of foreign agricultural commodities are long overdue changes that simply need to be made. One can take a number of paths to arrive at the conclusion that products banned from use in this country also ought to be banned on products imported into this country. It is a health issue, a food issue, and it is a fair trade issue. It is manifestly unfair to farmers in this country to let their overseas competitors continue to use products banned in the United States. I would change this provision in a small, but important way. As written, it provides an exemption for those products which are cancelled or withdrawn from use solely for environmental reasons. It really does not matter why a product is cancelled, unfair competition is unfair competition. There is simply no acceptable justification for any exception to the basic principle embodied in the general provision.

Besides these five points, I would like to explore the question of budgets for just a moment because I forsee some problems there. The system of regulating pesticides in the U.S. depends very heavily on voluntary compliance of "trained" or "under-supervision" personnel. Training is costly and there is not enough money for that; there never has been. As a result, not enough training is done. It is just that simple. Likewise, funding for State enforcement programs is insufficient to deal with the problem. It is remarkable that the proposal for reregistration includes fees to begin to cover some of the costs of registration per se. Current levels of funding, and I am afraid likely future levels as well, are simply insufficient to cover needed training and enforcement. It is surely more costly to "do without" the training enforcement, the cost can be counted in personal injuries, contaminated water, and environmental damages. The money has to be found, perhaps through an expanded set of fees of some other mechanism. While the budget is not the main purpose of this hearing, the point is too important to omit it altogether.

Conclusions

It is clear that this bill solves some very real problems, a few of which I have noted above. Therefore, it needs to be passed. It would be a substantially better bill if the remaining items can be worked out through some mechanism so that a more thorough set of reforms can be accomplished. If that cannot be done, however, then you should pass the agreed-to-amendments.

Second, it is not enough to simply pass a bill. This administration, the next administration, and the ones after that must know that the Congress is going to insist that the work be done. Most importantly, the failure to reregister old products is a national scandal which must cease. There must be an adequate budget at EPA and adequate funding to the States for enforcement and training.

STATEMENT OF JAY FELDMAN
NATIONAL COORDINATOR, NATIONAL COALITION AGAINST THE MISUSE OF PESTICIDES

BEFORE THE

COMMITTEE ON AGRICULTURE, NUTRITION AND FORESTRY
U.S. SENATE

APRIL 22, 1986

Mr. Chairman and members of the Committee. I am Jay Feldman, National Coordinator of the National Coalition Against the Misuse of Pesticides (NCAMP), a national, nonprofit, membership organization that represents community-based organizations and pesticide poisoning victims seeking to improve protections from pesticides and promote alternative pest management strategies which reduce or eliminate a reliance on pesticides. Our membership spans 48 states, Canada, Mexico, as well as other countries around the world.

We appreciate the Committee's interest in developing a comprehensive legislative responsive to the pesticide poisoning problem and are happy to work with you to this end.

If we are to confront successfully the pesticide problem, we must address two sides of the poisoning equation. One side of the equation governs the complete testing and regulation of pesticide ingredients. The other side regulates pesticide user training and certification as well as enforcement of the law. To address either side of the equation and not the other will result in unacceptable human and environmental exposure. Whether a pesticide is poorly tested and regulated or well regulated and improperly used, the result is the same --people will continue to be poisoned.

The results of poisoning vary from short- to long-term human health effects, from acute symptoms such as headaches, nausea, sweating to chronic effects such as cancer, birth defects, and nervous system disorders. The health effects of pesticide exposure are now well documented in various government and scientific reports and the inadequacies in the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) have led to documented human hardship in certain groups and increased exposure of the general population to untested poisons. A January 1981 report issued by the Council on Environmental Quality, Chemical Hazards to Human Reproduction, cites various studies of male and female workers exposed to pesticides. These studies report impotence, chromosome aberrations, infertility, miscarriages and other adverse effects on reproduction.

Of importance to this Committee in particular is a University of

Iowa study in 1982 which found that Iowa farmers faced greater risks of six types of cancer than city dwellers. (Burmeister, "Cancer Mortality in Iowa Farmers, 1971-78", 66 J. Of Nat'l Cancer Inst. 461 (1981).) According to the researchers, the cancer rate is an occupational hazard of farming not related to smoking and is confirmed by other studies around the world.

One of the most controversial and distressing aspects of the nation's 2 billion pounds of annual pesticide use is the alarming extent to which these toxic chemicals --which unlike most toxics, are intentionally and legally disseminated into the human environment-- remain untested for carcinogenic, mutagenic, and teratogenic effects. A report published in 1982 by the staff of a congressional subcommittee confirmed a decade of similar investigations, finding that 79 to 84 percent of pesticides lacked adequate carcinogenicity testing, 90 to 93 percent lacked adequate mutagenicity testing, and 60 to 70 percent lacked adequate testing for their tendency to cause birth defects. (EPA Regulatory Program Study, Hearings before the Subcommittee on Department Operations, Research and Foreign Agriculture of the House Comm. on Agriculture, 97th Cong., 2nd Sess. 77 (1982) (staff report).)

More recently, in 1984, the National Academy of Sciences found that complete health hazards assessments for pesticides and inert ingredients of pesticide forumlations are possible for only 10 percent of pesticides in use. (National Research Council, National Academy of Sciences, Toxicity Testing: Strategies to Determine Needs and Priorities 118 (1984).) Many other problems exist, including a poor EPA enforcement record, extensive use of special exemptions from product registration requirements, drawn out administrative safety reviews, inadequate applicator training and certification, and major use problems that result in food, ground-water, and living and working space contamination.

Despite these problems and unknowns, exposure to pesticides is widespread and growing. The public is routinely exposed to pesticides through the food supply. A study on Long Island, New York found that of the 1,100 homes surveyed 33 percent were contaminated with chlordane, which is used for termite control. (Dr. Nancy Kim, Director, Bureau of Toxic Substance Assessment, N.Y. State Dept. of Health, Testimony before the Dept. of Envt'l Conservation 3 (Albany, N.Y. Apr. 4, 1984).) Ground-water contamination has been detected by EPA in 23 states. (S. Cohen, Ground-Water Monitoring of Pesticides in the U.S.A., Abstract No. TEST-34, presented at the 189th Nat'l Mtg. of the American Chemical Society (Miami Beach, FLa. Apr. 30, 1985).) Community spray programs for mosquito control and other pests are widespread as is forestry and right-of-way spraying. Chemical lawn services have been growing. One such company, Chemlawn, according to news resports, has increased annual sales from $87 million in 1979 to $227.7 million in 1984 with 1.3 million customers in 42 states and Canada. (Brooks, "Dispute Erupts Over Lawn-Spray Dangers," Wall St. J., Oct. 11, 1984, at 35; Gram, "Growing Lawn-Care Field Scares Environmentalists," Cleveland Plain Dealer, Feb. 19, 1984. This, on top of normal household use of inadequately tested pesticide products, suggests astoundingly high rates of pesticide exposure.

While pesticide poisoning from time to time has emerged on the front pages of our nation's newspapers, this Committee has never attempted to relate these poisoning incidents or contaminations to deficiencies in the pesticide law. As time has passed, the pesticide problems have mounted with little explanation of where pesticide policy has been deficient. This committee did not explore the deficiencies in the system that led to the 1981 contamination of game meat in Montana and the west, the 1983 EDB contamination of the nation's grain-based food supply and the ground water of a half dozen states, the 1984 documented chlordane contamination of a third of the homes surveyed on Long Island, New York, the 1985 temik (aldicarb) contamination of watermelons, and most recently last week's heptachlor contamination of the milk supply of eight states. On top of this, EPA has documented ground-water contaminated by 17 pesticides in 23 states. The state of California reports 57 pesticides in the ground water of 28 counties. Are we being asked to simply except these poisonings and the thousands or hundreds of thousands of others that have gone undocumented?

Increasingly people are being warned not to eat a particular product or to take precautions when preparing game fish. I have attached a copy of a sign that appears on the docks along the Great Lakes and serves as an example of the current state of fish contamination in that area. The sign warns those game fishing to minimize intake of toxic chemicals in the fish by removing all skin, cutting away a v-shaped wedge along the entire length of each side of the fish and cutting away the dorsal fat along the backbone and the fat belly meat along the bottom of the fish. Pesticides account for a significant amount of the contamination that has created this situation.

NCAMP believes that we must now consider these incidents and respond to these problems as the Committee considers the pesticide issues and reauthorization of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). It is our belief that S. 2215 by itself will not stop the poisoning of America's homes, drinking water food and farms. Because of this, NCAMP urges the Committee to include in its final bill provisions to control poisoning due to applicator misuse, spray drift, the use of untested pesticides under special local permits, indoor application of pesticides, farmworker protection and non-enforcement of existing law. Before exploring these points, I would like to provide some background on our support for the industry/environmentalist compromise on the registration issues contained in S. 2215.

The Nature of the Agreement as Contained in S. 2215

We have sought, with the Campaign for Pesticide Reform, to find an acceptable political solution to some of the widespread problems associated with the registration of pesticides. Similar to other parties to the agreement, we recognize the nature of compromises and the shortcomings of this one in particular. However, we also realize the political realities of passing legislation in an unfavorable political climate.

Needless to say, there are specific parts of the agreement that we would like to see improved, particularly in the areas of controlling false and invalid registration data, conditional registrations, preregistration access to data, fines, inerts, and export of pesticides. Similarly, the agreement does not address critical issues within its scope, also as a result of the negotiation process. As you know, S. 2215 is silent on critical issues such as the public's right to challenge EPA cancellation decisions as not protective enough and the repeal of the existing indemnity program which compensates manufacturers for losses associated with EPA cancelation decisions. S. 2215 does not alter the existing risk-benefit formula for registering pesticides which currently allows health effects to be outweighed by economic benefits too often undefined and unscientifically derived.

Having said all this, we are supporting the agreement reflected in S. 2215 as long as it is part of a package that will begin to tackle the pesticide poisoning problem in the terms cited below.

Training and Certification

Since the inception of a cooperative federal-state training and certification program in 1978, more than 1.5 million individuals have been trained and certified to handle chemicals identified by EPA as "restricted use" pesticides or, according to EPA, the most toxic class of compounds. Given underlying problems with the safety of products, the training program becomes more important when considering the problems associated with over application, lack of safety precautions and improper mixing, loading, storage and disposal of chemicals.

We feel that allowing untrained and uncertified persons to apply the most restricted class of pesticides, or any class of pesticides for that matter, is unprotective of the public health and the environment. Untrained handlers of dangerous materials have led to situation such as the Pratts of Nashua, Iowa whose dairy herd was virtually wiped out after an untrained applicator unloaded a tank of the pesticide atrazine in a roadside ditch adjacent to their farm in 1984. Since this incident, 6 cows have died, another 30 have had to be destroyed, 22 calves were still born or died soon after birth and milk production from the remaining cows dropped 75 percent.

The law must be strengthened in this area of certification and training and the existing loophole, allowing untrained applicators to operate under the supervision of those trained, must be stricken from FIFRA.

This supervision provision allows inexperienced applicators to go into people's homes and operate on farms with nothing more than phone contact, at best, with a certified applicator. Furthermore, the actual training of applicators must be upgraded with uniform national standards of health and safety information, standards for trainers and competency testing requirements.

Recordkeeping

Because pesticide use records are often not maintained, it is impossible for individuals trying to establish a paper trail to actually determine where a contamination or poisoning originated. While this may be the preferred scenario for the violator, it does not ensure that pesticide incidents can be documented and remedied. It does not ensure that the source of a serious problem can be determined. Without this information, those attempting to enforce the pesticide law are unable to do so.

Pesticide Drift or Chemical Trespass

The question of drift or chemical trespass is a basic question of human exposure and possible property damage. Pesticide drift has long been a public and environmental heatlh concern to those living near sprayed fields and forests as well as farms and rights-of-way. Community and suburban lawn care spray programs have resulted in substantial drift as well. Pesticides are not adequately labelled to control for chemical trespass, but simply instruct users in generally unenforceable terms to "avoid" drift. Studies show that as much as 50 percent and more of the sprayed pesticides may not land in the target area.

In a letter to a California state official, Larry Landis, a commercial cropdusting pilot with over 16 years experience wrote,

> . . .In the past 16 years, I have piloted aircraft for agricultural businesses. . .My experiences have led to the realization that the aerial spraying of agricultural chemicals is dangerously close to being completely uncontrolled with regard to health hazards. Applicators in California consistently spray homes, schools, hospitals, highways and waterways, and are virtually unsupervised by the Agricultural Commissioner's staff. . .Because of the lack of enforceable regulations, involuntary exposure to a wide variety of harmful chemicals has become part of the "American way of life!"

Legislation is needed to address this problem, as difficult as it is. Application technologies and standards governing use patterns, including buffer zones, must be adopted to address this problem, rather than ignoring it totally.

Special Local Need Permits

Section 24(c) of FIFRA permits a proliferation of chemicals tha have not been subjected to full and adequate health and safety testing. I would like to remind the Committee of a July, 1983 study that was presented to you by the Rural Advancement Fund of the National Sharecroppers Fund (RAF/NSF).

Using a sample of 2,089 special local need (SLN) registrations for 25 states (79 percent of all SLNs granted in 1981-1982), RAF/NSF found that: (i) more than 40 percent of all SLN pesticides registered in the past two years contain chemicals registered on the basis of invalid or fraudulent tests conducted by Industrial BioTest Laboratories (IBT). For example, IBT conducted the safety tests for the three most widely used SLN pesticides (Furadan, Sencor, Paraquat); (ii) a majority of the SLN registrations were issued for major crop use over a wide geographic area. More than 60 percent of all SLNs were issued for use on ten major crops; and, (iii) 90 percent of the registrations are obtained by chemical manufactureres. Five companies received 46 percent of all SLNs in 1981-1982.

Clearly, the abuses here, which continue, can be corrected with legislation which restricts the expanded uses of products that have not been fully tested and which are applied widely across geographic regions without any concern for the regional or national scope of the problem.

Indoor Exposure

The use of chemicals such as chlordane, which belongs to the organochlorine or DDT family, for termite control continues to attract a lot of public attention because of the widespread contamination of possibly millions of homes in the U.S. It is important to note here again the recent survey on Long Island, New York which found that of 1100 homes tested 33 percent were contaminated with chlordane.

Those with residues of chemicals in their home, experiencing chronic low level exposure, often exhibit symptoms of pesticide poisoning including headaches, muscle aches, nausea, sleeplessness and excitability. More severe illnesses associated with higher levels of exposure include convulsions, loss of consciousness, disorientation, personality changes, psychic disturbances, loss of memory and a variety of blood diseases. It is not uncommon, moreover, for those in a contaminated home to live with a constant fear of long term chemical effects.

Despite the real hazards associated with indoor expsoure, EPA has not set standards of safety to protect public health. Instead, for the termiticides, the National Academy of Sciences has established guidelines of not more than five micrograms per cubic meter of air. However, for the range of chemicals used indoors, most often guidelines do not exist.

In a January 17, 1983 letter explaining federal policy, former Deputy EPA Administrator, John Hernandez, said the setting of maximum residual levels or tolerances for pesticides with indoor uses is outside the Agency's legal authority. He stated, "Neither the Federal Food, Drug and Cosmetic Act, the FIFRA, nor any other pertinent statutes, provide for setting tolerances for residues of pesticides in air or on surfaces in buildings."

This state of affairs leaves the public unprotected. Legislation can easily rectify this major deficiency by simply requiring safe residue standards.

Farmworker Protection

Farmworkers, most often the first in the chain of exposure to pesticides, are the least protected. While EPA has published one page in the code of federal regulations for the protection of farmworkers, other workers of this country have secured workplace protection programs which recognize the need for safety procedures, training, equipment and enforcement. While farmworkers deserve this at a minimum, programs are needed, as well, to establish across the board reentry times to reduce exposure and medical surveillance to track potential health problems.

Without the statutory framework it does not appear that farmworkers will enjoy the basic human health protection that the rest of the population have come to expect in their workplace. Without the basic sanitation and handwashing facilities, farmworkers will continue to suffer higher rates of pesticide poisoning than the general public.

Private Right of Action to Enforce the Law

From an enforcement perspective, an October, 1981 U.S. General Accounting Office report, entitled Stonger Enforcement Needed Against the Misuse of Pesticides, (General Accounting Office (1981).) suggests that the public and the environment are not protected from pesticide misuse because EPA and state enforcement programs exhibit the following characteristics: (i) many enforcement actions are questionable or inconsistent; (ii) some cases are poorly investigated; (iii) some (state) lead agencies often do not share EPA enforcement philosophy; and, (iv) most states lack the ability to impose civil penalities. In fact, the existing enforcement system does not provide adequate public protection and recource for pesticide misuse.

We agree with those who would like to provide the public with an alternative means to stop label violations as well as damage or harm associated with pesticide use. The alternative available under almost all other pieces of environmental legislation, such as the Water Pollution Control Act, the Clean Air Act, the Noise Control Act, the Toxic Substances Control Act and the Safe Drinking Water Act, is a citizen suit provision or a private right of action. This would then enable, as one alternative, the enforcement of FIFRA through the U.S. District Court system.

Ground-Water Protection

With approximately 50 percent of the U.S. population relying on underground drinking water from aquifers, the protection of ground water from pesticides must be a national priority. While there are only six pesticides regulated under the national interim primary drinking water standards, it has become obvious that we must approach this growing problem with a preventive orientation. Cleaning up ground water is virtually impossible. At the least, measures must be instituted under FIFRA to restrict and relabel pesticides that have already shown up in the ground water. Premarket testing of new chemicals must ensure that chemical use patterns will not result in contamination. Finally, monitoring must be required so that quick action can be taken to preclude widespread contamination.

Local Authority

Because of the inadequate controls governing the testing and use of pesticides, local political subdivisions have begun developing pesticide notification systems to alert people in the community to the use of pesticides, associated hazards and protective steps such as reentry times. These measures have enabled local communities to use their police powers to establish a right-to-know standard to notify residents of pesticide spraying.

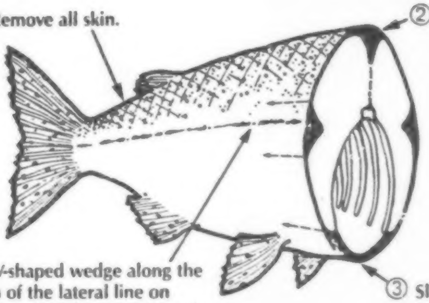
More and more communities are exerting their authority in this area of pesticide use. People are taking pride in their community's ability to address questions of right-to-know and take concrete steps which they feel are needed to protect their families. Any attempt to preempt this type of action would be unacceptable to those community groups and people currently working in this area or considering it.

Conclusion

The poor state of our pesticide control system has left the American public and importing countries unprotected. NCAMP has learned over the years how this statute and equally deficient state statutes have allowed applicators to render people's homes unliveable and created a litany of pesticide induced illnesses.

The time to act on this problems is past due. But, Congress must act to address both sides of the pesticide safety equation and improve the speed with which pesticides are tested while improving the requirements which govern pesticide use.

Cleaning Great Lakes Fish



① Remove all skin.

② Cut away dorsal fat along backbone.

③ Slice off fat belly meat along bottom of fish.

④ Cut away a V-shaped wedge along the entire length of the lateral line on each side of whole fish or on skin side of each fillet.

Some Great Lakes fish are contaminated with low levels of toxic chemicals. You can minimize your intake of these chemicals by properly cleaning, trimming, and skinning your fish. Follow the four steps.

Cooking does not destroy chemicals but the heat from cooking melts the fat in the fish, removing some chemicals. Do not use fish drippings in anything meant to be eaten. Discard fish drippings in the garbage.

For more information, contact the Michigan Sea Grant College Program–University of Michigan, 2200 Bonisteel Blvd., Ann Arbor, MI 48109, or 334 Natural Resources Bldg., Michigan State University, East Lansing, MI 48824. University of Wiscon in Sea Grant Institute (1800 University Ave., Madison, WI 53705)

APRIL 30, 1986 HEARING

STATEMENT OF HONORABLE EDWARD ZORINSKY
A U.S. SENATOR FROM NEBRASKA

Mr. Chairman, I am glad that the committee today is continuing this hearings to consider amendments to the Federal Insecticide, Fungicide, and Rodenticide Act.

These hearings are very important inasmuch as the effective regulation of pesticides is necessary to ensure the safety and productivity of American agriculture, the safety of our food and drinking water, and the control of disease, as well as protecting the environment. The issues involved in the pesticide regulation are numerous and complex.

Last week, we heard testimony from the Environmental Protection Agency and various other interested parties as to the necessity of proceeding in a timely fashion to complete the task of reregistration of pesticides that have not been subjected to a thorough scientific review. The failure to complete this process is of great concern to pesticide manufacturers, consumers, environmental groups, and users of both agricultural and nonagricultural pesticides, as well a Members of Congress.

The two bills before the committee, S. 2215 and S. 2346, would both ensure that the EPA will proceed with reregistration in a timely fashion.

In addition, there are number of other issues involving pesticide regulation addressed by these bills, sometimes in a diverse fashion. These concerns, among other things, (1) registration fees, (2) limiting farmer liability for pesticide use, (3) the establishment of uniform tolerance levels for pesticides in foods, (4) local regulation of pesticide use, (5) the continued availability of minor use pesticides that are important to the production of certain crops and products, (6) conditional pesticide registration, (7) the regulation of inert ingredients, (8) availability of information in the registration process, and (9) the manner in which household chemicals, especially antimicrobials, are treated under FIFRA.

Mr. Chairman, I look forward to reviewing the testimony of the today's witnesses.

STATEMENT OF HONORABLE MITCH McCONNELL
A U.S. SENATOR FROM KENTUCKY

Mr. Chairman, today the committee is hearing testimony from expert witnesses who share my concern about the FIFRA-NACA coalition bill. While we're all deeply concerned about the environment, we cannot ignore the one person this committee is trying to help: the farmer. This coalition bill, I'm afraid does that.

In 1972, when the FIFRA legislation was last revised extensively, no one with whom I've spoken has much good to say about the way EPA did business in this area. Since that time though, EPA had developed a meaningful pesticide testing program which has served both farmers and environment. It is not a good idea to totally eliminate EPA flexibility in dealing with changing agricultural problems and the coalition "compromise" moves too far in that direction. The bill sponsored by Senator Helms does a much better job of addressing these issues.

Another issue here which has been implicitly ignored is user fees. To accomplish the worthy environmental objectives of the coalition bill, the EPA will literally need an army to administer the new, expanded testing program. Financing this program will cost a fortune, so a user fee system will presumably be imposed. This kind of system is blatently unfair to smaller companies, especially a company which is unable to compete with a major pesticide manufacturer because of patent restrictions. Since smaller companies would be in a poorer position to pay such user fees, there would be a tremendous disincentive to test and produce new chemicals.

This concerns me a great deal, Mr. Chairman. The Southeast produces a lot of specialty crops--tobacco, peanuts, rice, cotton--for which special pesticides are called for. Many of the chemicals used are created on a specific needs basis by smaller manufacturers. I do not want to see this source of agricultural technology dried up because of financial considerations which have been indirectly imposed by the Congress.

Finally Mr. Chairman, let's not lose sight of our objective. The purpose of these extensive hearings is not to make it harder on America's farmers to use pesticides, but to make it safer for them to use pesticides. An unrealistically stringent testing deadline solves nothing and only aggravates the problem. I look forward to the testimony of today's witnesses on these issues.

STATEMENT OF HONORABLE PATRICK LEAHY
A U.S. SENATOR FROM VERMONT

Mr. Chairman, continuation of the hearings on amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) is necessary because the issues encompassed by the legislation are varied and complex and many environmental and agricultural groups have important comments to offer. The comments received from the witnesses today will help the committee in its mark-up of the proposed amendments to FIFRA that we hope to enact this year. I look forward to reporting the strongest bill possible.

Years of effort on the part of several organizations concerned about safer uses of pesticides have been devoted to formulating a FIFRA bill this year. I would hope that we can report a bill that rewards the efforts on the part of those groups. I would like to again point out that organizations supporting S. 2215, the bill I introduced with Senators Lugar and Proxmire, include the Campaign on Pesticide Reform--a coalition of 41 consumer, environmental, and labor groups--and the National Agricultural Chemicals Association, whose membership includes some 92 agribusiness firms.

Mr. Chairman, I look forward to reviewing the testimony of today's witnesses.

STATEMENT OF HONORABLE ALAN J. DIXON
A U.S. SENATOR FROM ILLINOIS

Mr. Chairman, I am pleased to be here this morning as the Senate Agriculture Committee begins its second full day of hearings on legislation to amend the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

FIFRA was enacted to protect farmers from ineffective and dangerous pesticides. Two pieces of legislation, S. 2215 and S. 2346, which would amend FIFRA are presently under consideration by this committee.

It is my hope that our witnesses will address their remarks to these pieces of legislation.

I look forward to the testimony to be presented this morning.

Thank you, Mr. Chairman.

STATEMENT OF HONORABLE WILLIAM PROXMIRE
A U.S. SENATOR FROM WISCONSIN

Chairman Lugar and Committee members:

Thank you for giving me the opportunity to testify on S. 2215, a bill which amends the Federal Insecticide, Fungicide, and Rodenticide Act. This landmark bill marks the first time that the chemical industry and environmental groups, longtime adversaries, have negotiated an agreement on any environmental statute.

The National Agricultural Chemical Association (NACA), representing 92 companies and the Campaign for Pesticide Reform (CPR), a coalition of 41 environmental, labor and agricultural groups met for over a year to produce this bill. They succeeded so brilliantly that both the bill's substance and process now serve as models for new legislative initiatives in the United Kingdom and European Community.

The agreement results from a series of compromises made by both sides. Neither got its full agenda. But their willingness to compromise should set the tone for our actions in the Congress.

While this unprecedented agreement deserves the support of this Committee and the Congress, it does not cover every important pesticide issue. Some remain under discussion by NACA and CPR. Others are still under negotiations between CPR and pesticide-user groups.

In 1983 and again in 1985, I introduced two versions of pesticide bills stronger than S. 2215. Those two bills contained much stricter deadlines for examining the most hazardous pesticides, those with strong evidence that they caused threats to public health. In addition, S. 2215 contains far more restrictive language regarding public access to health and safety data prior to registration than did my earlier legislation. These changes represent major concessions by environmental groups during the negotiations.

But even more important than these changes are omissions of entire major controversial areas dealt with earlier. Some of these, like groundwater contamination, are still the subject of ongoing NACA and CPR discussions. Others, such as farm worker protection, enhanced enforcement by EPA or private citizens, training of pesticide applicators and pesticide spraying protections, remain for resolution in CPR negotiations with pesticide-user organizations such as the Farm Bureau.

I hope that these issues can also become part of the deliberations of this Committee and that the groups involved will follow the lead of NACA and CPR in arriving at speedy resolution of their differences. However, I have little sympathy for groups on either side of the issue who declined to participate in negotiations and now seek to obstruct this process.

Groundwater protection remains the most important of all the unresolved issues. In my own state of Wisconsin, at least 14 different pesticides have been found in drinking water. But EPA set standards for only six of these pesticides, imparing state protection of our citizens.

Even worse, although Wisconsin has the nation's first strong state-wide groundwater protection law, the law depends, for its standard-setting, on information developed by EPA under the pesticide and the safe drinking water programs. Since over 70% of Wisconsin's citizens use groundwater for drinking, pollution of this resource is a catastrophe which disrupts even the most basic activities of life, like taking a shower or cooking a meal.

California, the market for about 1/3 of all pesticides, also recently enacted state-wide groundwater protection legislation. Here too, the state is at least partially dependent on information development and standard-setting by EPA for its own regulatory program. If EPA sets no standards, it cripples states which act responsibly to regulate where EPA fails to act.

The groundwater plan under discussion by NACA and CPR must set national health-based standards for any pesticide detected in groundwater, enforced by a mandatory regulatory program. The type of regulatory action should be proportionate with the degree of threat posed by the pesticide.

Mr. Chairman, my colleagues may wonder why I want strong pesticide laws even though I come from a major agricultural state. The answer is simple. Weak or shifting pesticide laws hurt farmers most of all. Farmers want predictability. They don't want to see produce banned from the supermarket. They need consumer confidence.

A pesticide program based on untested chemicals or fake data does not help them.

Even worse for Wisconsin and other dairy states is the threat of contamination of our herds. As the recent heptachlor tragedy in Arkansas and Oklahoma points out, dairy cows once contaminated by pesticides may result in a total loss for farmers. The cows can't be slaughtered for beef and may take as much as a year, if ever, to decontaminate--a year without income.

Mr. Chairman, I will say very little about the specifics of this agreement. Other speakers, I'm sure, will cover the points I have missed. However, I would like to make just a few points about the bill before I close my remarks.

With this bill, for the first time EPA will have enough scientific data to make reasoned decisions about a chemical's potential harm to human health and the environment: Decisions won't be ad hoc or based on guess work. Best of all, we will end the pesticide-of-the-month syndrom.

This bill will also prohibit closed-door decision-making and insure speed and openess in EPA procedures. It codifies the result in a case brought by the Natural Resources Defense Council, which ended the bad old days of secret meetings and secret agreements.

Finally, the bill contains a real first for environmental laws. It requires companies seeking to reregister products already on the market to pay EPA a fee of $150,000, partially defraying the cost of processing, an amendment totally in agreement with the best principles of budgeting.

I commend everyone who worked on this agreement and hope the Committee can complete its action during this Congress.

TESTIMONY OF RALPH ENGEL
PRESIDENT
CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION
BEFORE THE
COMMITTEE ON
AGRICULTURE, NUTRITION, & FORESTRY
UNITED STATES SENATE
APRIL 30, 1986

My name is Ralph Engel; I am president of the Chemical Specialties Manufacturers Association (CSMA) located at 1001 Connecticut Avenue, N.W., Washington, D.C. I am accompanied today by Dr. Warren E. Stickle, Director of Legislative Affairs at CSMA.

CSMA has a membership of more than 400 firms engaged in the manufacture, formulation, distribution, and sale of aerosols, antimicrobial products, automotive chemicals, detergents and cleaning compounds, pesticides, and waxes, polishes and floor finishes for household, institutional and industrial use. A significant number of these products have pesticidal claims and are, therefore, subject to EPA jurisdiction pursuant to the requirements of the Federal Insecticide, Fungicide and rodenticide Act (FIFRA), as amended.

Specifically, CSMA represents the non-agricultural pesticide industry, including disinfectants and sanitizers; home lawn and garden pesticides; and a wide variety of other pesticides for home, industrial and institutional use.

We applaud Chairman Helms for introducing S. 2346, the Pesticide Reform Act of 1986, a bill that reflects the interests and concerns of many agricultural and food groups, farm organizations, rural and urban pesticide user groups, and other manufacturers. We support this legislation and urge its adoption by this committee.

I would like to take this opportunity to commend you, Mr. Lugar, along with the committee for your continued interest and concern about FIFRA legislation.

We recognize the introduction of S. 2215 , as a set of FIFRA amendments developed by the National Agricultural Chemical Association (NACA) and the Campaign for Pesticide Reform (CPR). These amendments have made a contribution in bringing together one portion of the industry and several environmental, consumer and labor organizations. To this end these groups should be applauded for their efforts, for they have contributed to the FIFRA dialogue and thus the momentum for legislation.

CSMA CONCERNS WITH THE NACA-CPR PROPOSAL (S. 2215)

Although we support the language in S. 2346, we would like to compare and contrast several issues that are contained in both S. 2346 and S. 2215: A) reregistration timetables; B) reregistration fees; C) public right to know; D) inert ingredients; E) cancellation procedures; F) data disclosure to the States; and G) inspection of laboratories. Let me take a few moments to touch on each of these issues.

A. REREGISTRATION TIMETABLES

Nearly everyone agrees that the present EPA reregistration program is moving too slowly. Conversely, S. 2215 provides that the total reregistration process be completed within six and one-half years. We believe this timetable is unrealistic.

S. 2215 establishes a series of EPA mandated deadlines, without allowing the Administrator the flexibility to address potential problems. The NACA-CPR proposal is too severe since an active ingredient would be suspended if any data gap, no matter how insignificant, is not filled. As proposed, any unfilled "Outstanding Data Requirements", regardless of importance, would trigger a suspension. A pesticide registrant should be given an opportunity to discuss the Agency's determination of the existence or importance of missing data prior to a suspension hearing.

The Administrator, within 18 months, would have to process some 40,000 studies and notify all registrants of all outstanding data requirements, and give them four years, from the date of the notice, to fill all such outstanding data requirements. The Agency needs about twice this amount of time to realistically accomplish this task.

In addition, it requires that the Administrator "complete reregistration of each pesticide within one year of receipt" of the data, a very unrealistic goal. These reregistrations, however, will not be evenly spaced over a six-year period. In fact, most data will be completed in the last two years of the six and one-half year cycle, forcing the EPA to attempt to reregister a disporportionate number of products in a very short time. It is unlikely that EPA could comply with these unrealistic deadlines and still comply with its other mandates. The Administratror should be given sufficient time to adequately address the reregistration process, with built-in flexibility to deal with unexpected problems in the system. Pursuant to the investigative and oversight congressional functions, the House and Senate can periodically examine the process to determine if any abuses are taking place.

We would propose the approach suggested in S. 2346. First, we recommend that registrants be given an opportunity to speed up the reregistration process and remove some of the burdens that have been placed on the agency. Specifically, the registrants could submit a list of outstanding data requirements to the Agency, within 6 months of the notice in the Federal Register. It would save the Agency time and resources, but still leave the final authority in the hands of the Administrator.

Second, the Agency ought to be given at least 36 months, not 18, to process about 40,000 studies. This proposal gives EPA more flexibility and allows the Agency to establish its priorities. In addition, the list of outstanding data gaps could be done on a staggered schedule, after the 12th, 24th, and 36th months. By establishing three different stages, it is possible to:

1. Expedite the release of the initial list (top priority) by six months.
2. Spread out the list development task for EPA over 3 years.
3. Provide that the studies and tests will be done on a more staggered basis, thus easing some of the problems of laboratory availability.
4. Provide that the data will come into EPA at various times so that the Agency review could also be staggered over time, rather than in a limited 1-2 year time period.

Third, under the provisions of S. 2346, the Administrator should be given more flexibility by defining the "extraordinary circumstances" by which he can extend the time limit, including non-negligent loss of laboratory results, destruction of the laboratory, unavailability of laboratory facilities, major animal loss or similar unanticipated problems.

Fourth, since the Administrator cannot reregister a product in one year from the date he has obtained all the required data, he should be given an extra year and if necessary a further two-year extension for "extraordinary circumtances."

We believe the Agency can complete the reregistration process in nine to ten years, if the registrants help by identifying data gaps, if the list of data gaps is released in a staggered process over three years, and if the data are processed over three years. The Agency would be able to spread out its manpower and other resources if the timetables contained more flexibility. S. 2215 builds into the process two major manpower surges one at either end - reviewing the 40,000 studies and processing the data. If these peak loads were more reasonably distributed, as in S. 2346, the Agency will have an opportunity to utilize its existing resources to accomplish the reregistration task without the need for fees.

B. REREGISTRATION FEES

Any system of reregistration fees would, in effect, result in taxing a few to finance a regulatory system that benefits many. When government services benefit society generally, the expense of those services must be borne by the taxpayers at large, not by individuals. The primary purpose for requiring the reregistration of pesticides is to protect public health and safety. Thus, the EPA reregistration process benefits the general public, not just those who produce products to be registered. These reregistration costs should be paid with public funds, not with special fees.

For many decades there have been special kinds of user fees for individuals, organizations, or companies that have sought special benefits. Visitors to national parks have paid an entrance fee to help defray the upkeep of the park and its facilities. Boaters have paid some user fees for use of canals and the inland waterways. Farmers and cattlemen have paid user fees for grazing on public lands. Each of these individuals, organizations or companies have derived specific levels of benefit by utilizing government facilities. We believe that these user fees should be required.

Under the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), there are, however, requirements for the preclearance of specific commercial products - drugs and pesticides - prior to their manufacture, sale and distribution. In each case the Federal Government acts as a clearing house, collecting and evaluating data, and ultimately making the decision of whether or not to grant registrations for pesticides or new drug applications. In each case the registration and preclearance of products broadly benefits the general public.

Pesticides should not be singled out for special user fees when other preclearance statutes are specifically exempted from user fees or registration fees.

The Congress has consistently taken steps to prohibit user fees for the registration of drugs, thus setting a clear precedent.

In passing the Federal Food and Drug Administration's budget for FY '85, the Congress specifically replaced $5 million that FDA had indicated would be made up through the imposition of user fees. In replacing these funds, the report of the House Appropriations Committee stated that FDA had received no funds "for further consideration or development of a user fee proposal." Congress' reinstatement of the $5 million in FDA's appropriations, coupled with the committee report, was tantamount to a specific legislative directive that Agency funds not be spent to develop a user fee proposal.

On December 13, 1985, the House and Senate conference committee voted to prohibit the Food and Drug Administration from imposing user fees for review of new drug applications for FY '86. The conferees accepted the House prohibition against user fees, contained in H.R. 3037, the Agricultural, Rural Development, and Related Agencies Appropriations Bill.

S. 2215, however, calls for a new section 3 (g) (10) requiring that "the Administrator shall charge and collect from the registrant or registrants of pesticides listed for reregistration pursuant to subparagraph (2) a one time fee of $50,000 for each active ingredient registered for use on food or feed" so that the Administrator can compile a list identifying data requirements. It also states that "(t)he Administrator shall collect an additional one-time fee of $100,000 from the registrant or registrants for each active ingredient for use on food or feed to be reregistered" so that the Administrator may "accomplish the subsequent data evaluation and reregistration of pesticides..." Section 3(g)(10) further stipulates that "for active ingredients registered solely for uses other than for food or feed, the Administrator may levy a reduced fee, but no less than one-half of the fee levied with respect to products registered for food or feed."

We oppose the adoption of reregistration fees for other reasons as well. First, a system of pesticide reregistration fees would dramatically increase product development costs, reduce innovation and have an unfair and disproportionate impact on small businesses. Second, by establishing only a flat fee, there is insufficient differentiation between agricultural and non-agricultural products. Third, the fee is not based on the actual time it takes EPA staff to register the product. Fourth, there is no exception for antimicrobial products or minor use products, including those for both agricultural or non-agricultural uses. Fifth, the ultimate costs of a reregistration fee program may, in part, be borne by pesticide users and consumers in general, and farmers in particular. We support S. 2346 since it contains no proposal for reregistration fees.

ANTIMICROBIAL PRODUCTS:

Many CSMA manufacturers produce disinfectants and sanitizers (antimicrobial products) registered under FIFRA. These products contain active ingredients for home, institutional and dairy farm use in the cleaning and sanitizing of laundry, medical equipment, lavatory facilities, milking equipment, etc.

Registered antimicrobial products cover a broad range of use patterns including use as sterilants, air and surface sanitizers, disinfectants, bacteriostats, fungicides, virucides and industrial preservatives. They are used in many areas such as in and around homes, medical facilities, schools, and industrial and food processing plants. Antimicrobial are used to treat surfaces/areas/objects including but not limited to floors, tables, walls, appliances, surgical instruments, medical devices, eating/drinking utensils, food processing equipment, laundry, drinking and processing water, air, processing and industrial fluids such as cutting oils and fuels; and to chemically impregnate items such as clothing, mattresses, carpets, plastics processed into various end use objects, and paper products such as tissues and toilet seat covers. These products are marketed as powders, tablets, bars, liquids, and sprays.

Some manufacturers register between 20 and 35 active ingredients for antimicrobial products, each with a slightly different molecular composition, different use and different EPA registration number. Under language incorporated in S. 2215, each one of the approximately 300 individually registered antimicrobial active ingredients would be assessed a reregistration fee of at least $75,000 and likely up to $150,000 per regfstration. Many small manufacturers, with gross sales of $5 million or less, will face a potential fee of up to $150,000 on each of the active ingredients they have registered. In these cases, the potential fee would be almost 10 percent of the company's annual gross sales.

Before preceedings with the reregistrations of these 300 antimicrobial active ingredients, an assessment has to be made as to whether or not the data requirements and/or reregistration fees would have a significant negative economic impact on the industry and a significant resource impact on the agency.

The agency is attempting to grapple with this difficult problem and should be applauded for its efforts. It is trying to gather exposure data based on use patterns, and is considering grouping similarly structered antimicrobial wherever possible, such as phenols or quaternary ammonium compounds, so that data could be developed on a representative in each groupings, rather than for every single entity.

In addition the EPA is discussing the possibilities of establishing different levels of toxicological data so that a system of sequential testing, perhaps in three phases, could be established. The agency should also be given the authority to waive, for economic reasons, some of these data requirements.

A recent preliminary assessment concluded that based on the production and distribution of some 350 million pounds of active ingredients, only 21 disinfectants, or about 15% of all antimicrobial products, could afford a full chronic test battery. Thus, the impacts on the industry appear to be substantial. Between 62 and 85% of the A.I.'s would drop out of the market or apply for data waivers based on economics. This group represents a very small proportion of the active ingredients used (between 0.6% and 2% by volume).

Conversely, about 15% of the antimicrobials product account for about 99% of the active ingredients used by volume. In other words about 230 of 300 antimicrobial active ingredients produce only 2% of the volume usage. These products which may account for as little as 10,000 pounds_and cannot support either extensive data requirements or reregistration fees.

These reregistration fees will, in fact, control which antimicrobial products will be available in the marketplace. Registrants of some products may choose to accept voluntary cancellation rather than paying reregistration fees. Certainly the proposed fees will not curtail the reregistration of very high-volume antimicrobial pesticides that are profitable. Access to some older products, with limited volume and specialized uses, for which the market is relatively small, may disappear because of the fees. If the fees make it unprofitable for the registrants of these products to reregister them, a vast number of antimicrobial products will be unavailable to manufacturers, users, and consumers. In our judgement, fees should not determine the availability of products.

MINOR USES:

The NACA-CPR reregistration fee proposal does not take into consideration "minor uses". Minor use can be divided into two segments: 1) minor use for agricultural crops, including but not limited to fruits, vegetables, nuts, and other small crops, and 2) "minor use" of non-agricultural pesticides.

Since there are no provisions for "minor use," in S. 2215 many agricultural users will be faced with no way to protect their crops, because many manufacturers will find it unprofitable to produce low volume, low profit products for "minor use" if they have to pay large reregistration fees. It would preclude other manufacturers from even entering the market.

With respect to "minor use" of non-agricultural pesticides, many of the active ingredients comprising these products are used for other purposes in addition to pesticides and are subject to regulation under the Toxic Substances Control Act (TSCA). If unrealistic reregistration fees are imposed upon basic producers, it will result in a withdrawal of important active ingredients from the pesticide market with diversion elsewhere.

Not only will existing products be affected by reregistration fees, but future products, on the cutting edge of technology, might be curtailed unless marketed on a high volume, high profit basis. Innovation for pesticide and antimicrobial products could be severely affected.

Lastly, if such a reregistration fee were coupled with a newly proposed registration fee ($163,000 for a new chemical, $29,000 for a new use, etc.), and sharp increases in existing registration fees at the state level, the costs of registering products will significantly increase. All those groups, organizations and individuals who manufacture, sell, distribute or use pesticide products will be directly or indirectly affected. Consequently, we respectfully request that the user fee program not be considered.

C. Public Right-to-Know

S. 2215 proposes that the registrant shall submit to EPA a fact sheet which contain the names of the pesticide active ingredient and troublesome inerts, including a summary of relevant health, safety and environmental data. The proposal also stipulates that EPA and the registrant shall make this fact sheet, which is similar in form and substance required in Material Safety Data Sheets, available to the public upon request.

Although we fully support the concept of sharing this information with the public, we believe that the state or state agency, as described in S. 2346, would be a more effective way of collecting and distributing information about pesticides.

In fact, the state could handle its share by distributing these fact sheets. If each of the 65,000 registered products contained a three-page fact sheet, the agency would have the unnecessary administrative burden to collect, store, categorize, retrieve, and dispense nearly 200,000 pages to the general public. At a time of budget cutting, there is no need to impose an additional paperwork burden on the agency's resources.

In addition, S. 2215 requests that legislative history stipulate that the three-page fact sheet contain information similar to a Material Safety Data Sheet (MSDS). Rather than requesting each registrant to create a new document that duplicates the MSDS, S. 2346 simply requires the registrant to submit an MSDS to the State or State Agency for distribution to the public.

D. Inert Ingredients

Recently the Environmental Protection Agency has substantially increased its interest in inert ingredients. We support the Agency's effort "to focus its attention on those inert substances that are most likely to cause health problems."

As previously stated in the testimony of Dr. John Moore, Assistant Administrator for Pesticides and Toxic Substances, EPA, on April 22, the agency has just released its draft "Strategy for Regulation of Inert Ingredient Used in Pesticide Products." The agency has established four levels of inerts and has set priorities for addressing them.

We commend the agency for taking these important initiatives and believe that is effectively moving within the regulatory arena to address troublesome inerts. The agency has asked for only 3 legislative changes on inerts: 1) "legislative clarification of its authority to list certain inerts on product labels," 2) "require data necessary to evaluate them," and 3) "favor limiting the size of the list of inerts."

Since the Senate committee may want to consider legislation that attains these objectives, we would like to review carefully the differences between S. 2215 and S. 2346.

Although we share the NACA-CPR and EPA concerns that the Agency ought to address those troublesome inert ingredients causing an end-use pesticide to be a hazard to man or to the environment, we differ with the approach taken in S. 2215. We would like to identify five basic concerns with this proposal:

1. Inert Criteria

We disagree that widespread exposure or use should alone be a trigger to the listing of inert ingredients, thus requiring additional testing. An inert ingredient should be listed only if a risk assessment or hazard evaluation indicates that a significant hazard may exist from the use of the pesticide product.

The NACA-CPR document stipulates that the Administrator shall publish a priority list of inert ingredients that fall into two categories. First, "inert ingredients which appear to cause a pesticide to meet or to exceed a criterion for initiating an interim administrative review" would be placed on the list. Second, "inert ingredients for which additional data are reasonably necessary to evaluate whether the inert ingredient may result in a pesticide causing an unreasonable adverse effect on the environment," would be listed as well. It would also add such ingredients (within a pesticide) if "there is significant and widespread exposure, or it is in widespread use, in pesticides."

Under the second category, widespread exposure or use alone should not be a trigger to listing an inert ingredient under subsection (h). A pesticide containing an inert ingredient should be listed under this subsection only if a risk assessment or hazard evaluation indicates that a significant hazard may exist from the pesticide use.

2. Agricultural and Non-Agricultural Differences

Since S. 2215 does not include any provisions for the Administrator to take into consideration the difference between agricultural and non-agricultural pesticides when establishing the priority list of inerts, we believe that a new subsection 3(h)(2) should contain language similar to that already set forth in section 25(a)(1) of existing FIFRA. The language, contained in S. 2346, reads as follows:

> "In establishing a priority list of inert ingredients under subsection (1), the Administrator shall take into account the differences in concept and usage between various classes of pesticides and the differences in environmental risk and the appropriate data for evaluating such risk between agricultural and non-agricultural pesticides."

3. The Dynamic List of 50 - 75 Inerts

S. 2215 provides for an initial list of 50 inerts, with 25 more to be added. This list is supposedly dynamic, with inerts coming on and off the list. The ultimate purpose is to establish a system by which the Agency could review and require testing on more than a thousand inerts over the next decade.

By establishing a minimum floor of 50 inerts, the Agency will be forced to review inerts that the Administrator might not have chosen to examine, because they do not pose a risk to man or the environment. The development of an unlimited inert list is resource intensive and will divert considerable agency resources away from other tasks, including registration and reregistration programs.

By establishing a ceiling of 50 inerts, as in S. 2346, but no minimum amount, the Agency could examine any troublesome inert without being forced to consider some 1,200 or more inerts. It would allow the Administrator to retain his flexibility, to establish priorities, and to deal effectively with ANY INERT that presents a hazard to man or to the environment. We would recommend substitute language that would read as follows: "the priority list shall consist of not more than fifty (50) inert ingredients."

4. Additional Data for Inert Ingredients

Although we believe that additional data should be generated for those troublesome inerts that might present a hazard to man or to the environment, the Administrator already has sufficient authority under FIFRA Section 3(c)(2) to require the generation of any necessary studies.

There is, therefore, no need to create a new elaborate Data Development Plan (DDP) for each inert ingredient in a pesticide that the Administration may consider.

A DDP program as outlined in S. 2215 would divert Agency resources away from the registration and reregistration process. For example, under subsection 3 (h)(7)(A)(ii), the Administrator would be required to construct a detailed DDP for all inerts he proposed to list under subsection 3 (h)(1)(B), even if the Administrator were later to determine that additional data was unnecessary.

We further suggest that the additional data collected under Section 3(c)(2) be subjected to a risk assessment.

5. Labeling of Inerts

We share the NACA-CPR concerns that troublesome inerts should be placed on the label if they cause an end use pesticide to create a hazard to man or to the environment.

If a risk assessment were to demonstrate that a significant hazard to man or to the environment exists, the inert ingredient causing a pesticide to be listed under Section 3 (h)(1) could be listed on the label. We agree that if the Administrator believes, after a risk assessment, that a potential troublesome inert ingredient may cause an end-use pesticide product to create a hazard to man or to the environment, the Administrator should act quickly to address the potential problem.

This provision would complement the existing authority of the Administrator. The Administrator has previously requested that products containing methanol (more than 4%), carbon tetrachloride and chlorofluorocarbons (CFCs) be so identified on the label, that certain products containing petroleum distillates (when inert and more than 10%) carry a warning on the label, and that all products containing sodium nitrate stabilizers be identified on the label. In essence, the Administrator has the authority to act quickly if he sees a potential hazard, or if he feels that a troublesome inert poses an unreasonable risk to man and to the environment.

Consequently, we believe it is possible to retain the essential elements of the NACA-CPR inert provisions, including: 1) a priority list on inert ingredients that may require additional testing; 2) provisions for requiring additional data; and 3) the requirement that the troublesome inert, so listed, be placed on the label.

We suggest, however, that the list be based on a risk assessment or hazard evaluation to see if a significant hazard exists. We request that a ceiling be placed on the number of listed inerts (50), but no floor so that the Administrator can address any inert he feels is troublesome, without having to process 1,200 or more over the next decade. We suggest that requests for additional data on inerts be restricted to the Administrator's existing authority under Section 3 (c)(2) so that the Agency does not have to construct a new, detailed Data Development Plan for each inert the Administrator proposes to list. Further that the data collected under this provision be subjected to a risk assessment.

E. Cancellation Procedures

Nearly everyone agrees that the cancellation procedures have taken too long and should be streamlined. The NACA-CPR proposal, however, interjects new controversies into this process at several levels.

Although the proposal retains the language of the Grassley/Allen Amendment, (FIFRA Section 3 (c)(8)), in its entirety, it adds a new paragraph that undercuts its meaning, establishing a risk-only trigger for starting an interim administrative review. Since nearly all products have some level of risk, it is extememly difficult to work with a zero risk concept.

We suggest that the zero risk trigger be replaced by the criteria developed by the EPA. During 1984 and 1985, the Agency developed a final rule, which it published in the Federal Register on November 27, 1985, containing a detailed criteria for a Special Review. Since this criteria has had ample opportunity for public comment and review prior to becoming a final rule, we recommend this language as a replacement for the trigger in S. 2215.

It is important to note that the Administrator still has the emergency authority to act in a crisis to eliminate the notice requirements of FIFRA Section 6(b) and go directly to suspension. The provision of existing Section 6(b) provides "in the event that the Administrator determines that suspension of a pesticide registration is necessary to prevent an imminent hazard to human health," then he may waive the notice requirements. Thus, the Administrator already has appropriate existing authority to act in a crisis or emergency.

We are also concerned about the shift to informal rulemaking contained in S. 2215.

The NACA-CPR agreement would allow the Administrator to "change the labeling of a pesticide by informal rulemaking."

The right of a pesticide registrant or user to examine EPA's proposed restrictions in a cancellation hearing is one of the major strengths of FIFRA. This procedure allows those who have invested time and money in registering a pesticide, and those who depend on the pesticide to protect their property, to examine the scientific basis for EPA's proposed restrictions. This process is the best method in any environmental law for assuring a proper, scientifically sound, decision. The NACA-CPR proposal would allow EPA to bypass the cancellation hearing, a hearing that must be available to registrants and users as a final resort.

The NACA-CPR proposal to add a new "informal rulemaking" as an alternative to a cancellation hearing allows EPA to impose pesticide restrictions without allowing interested parties to go to a cancellation hearing. In short, EPA could, through an "informal rulemaking", impose restrictions on a pesticide and neither the registrants nor the users would have an opportunity to dispute them in a cancellation hearing. If the Agency has some concern about a pesticide, it should initiate a Special Review or a cancellation hearing, but it should not deny the registrant or user recourse to the cancellation hearing.

Although we support the concept of shortening the period for a cancellation hearing, the arbitrary 12-month limit from initial notice to Administrator decision, contained in S. 2215, will prove unworkable in many cases. That time limit would be difficult to meet even if it were from the time of the notice until the time of a decision by the hearing examiner. The 18-month limit contained in S. 2346 would be workable in most cases.

F. DATA DISCLOSURE TO STATES

Although nearly everyone agrees in principle that the State or State agencies should have access to registration data, the NACA-CPR proposal creates a new subsection 10(H) that provides for the disclosure of "any data or information acquired under the authority of this Act if the laws of the state assure that the owner of the data or information will receive no less protection with respect to the disclosure and use of the data or information by the state than is provided by Sections 10 and 3 of this act". Since many states have laws inconsistant with each other as well as Federal FIFRA, it is unlikely that states could take advantage of this section without changing many of their own laws, a difficult and time consuming approach.

According to the provisions in S. 2346, we recommend that the State or State agency enter into a written cooperative agreement with EPA so as to certify that anyone denied access to the information at the federal level would also be denied access at the state level. Thus, it would be possible to get the appropriate data to the state or state agency without jeopardizing the confidentiality of the data or forcing each state to change its laws to conform to federal FIFRA.

In addition, it is not possible to provide FIFRA data to the states or state agencies by simply asserting that states shall have access to the information. The existing data files are not properly organized to facilitate the location and retrieval of information in a timely and effective manner. The data must be organized by: 1) pesticide name; 2)Chemical Abstracts Service registration number; 3) plant site; and 4) submitters. Thus, a state could request a list of plants in their state that produce a specific product. Under the present system, EPA is not prepared to comply with this kind of request.

G. Inspection of Laboratories

Although we share the NACA-CPR concerns about the need for inspection of laboratories, we favor the language included in S. 2346.

II. CSMA CONCERNS ABOUT ADDITIONAL FIFRA ISSUES

In addition to our concerns about the S. 2215, we at CSMA believe that several other issues contained in S. 2346 ought to be addressed while we pursue FIFRA amendments in 1986.

A. State Political Subdivision Under Section 24 (a)

During the 1980's many political subdivisions of a state, such as a city, county or township, have attempted to exercise the same pesticide jurisdiction as a state. Such attempts to usurp the authority of the state are contrary to the legislative history of FIFRA. In passing the 1972 FIFRA amendments, Congress granted limited pesticide regulatory authority to states. The legislative history shows that Congress intended, in some cases, to share its authority with the states, but not with local jurisdictions.

While the language of a statutory provision may be open to conflicting interpretations, the intent of Congress, as documented in the legislative history, is used to determine how that provision is to be construed.

In adding Section 24(a) to FIFRA in 1972 (Public Law 92-516), Congress made clear that it was extending limited regulatory authority to the states, but not to local jurisdictions. On June 7, 1972, the Senate Agriculture Committee reported out the previously passed House bill. The committee report (Senate Report No. 92-838, 92nd Cong., 2d Sess.) accompanying the bill states:

> The Senate Agriculture Committee considered the decision of the House Committee to deprive

> political subdivisions of States and other local authorities of any authority or jurisdiction over pesticides and concurs with the decision of the House of Representatives. Clearly, the fifty States and the Federal Government provide sufficient jurisdictions to properly regulate pesticides. Moreover, few, if any, local authorities whether towns, counties, villages, or municipalities have the financial wherewithal to provide necessary expert regulation comparable with that provided by the State and Federal Governments. On this basis and on the basis that permitting such regulation would be an extreme burden on interstate commerce, it is the intent that Section 24, by not providing any authority to political subdivisions and other local authorities of or in the States, should be understood as depriving such local authorities and political subdivision of any and all jurisdiction and authority over pesticides and the regulation of pesticides. 3 U.S. Code Cong. & Ad. News, p. 4008 (1972).

The Senate Commerce Committee offered an amendment to that bill specifically to allow local jurisdictions to regulate pesticides, and the Senate rejected it by a vote of 71-0.

Despite this extensive legislative history, there have been attempts by various political subdivisions of fifteen or more states to regulate the sale or of use pesticides or to request generation of new data. Local jurisdictions are enacting restrictions that create considerable hardships for farmers, foresters, and homeowners, as well as for manufacturers.

Local regulations not only place burdens on pesticide users, but are unnecessary in light of the extensive system of state and federal regulation. Local jurisdictions are also not equipped to make the scientific judgements needed to regulate pesticide use properly.

To solve the problem of local pesticide regulation in the 1980's, we recommend an amendment to Section 24 (a) of FIFRA, contained in Title XIX of S. 2346, to limit pesticide regulatory authority to the states. With this amendment, the section would read: "A State, but no political subdivision of a State, may regulate the sale and use of any federally registered pesticide . ."

We support this amendment and believe that the statute ought to reflect the Congressional intent that political subdivisions below the state level should not regulate the sale or use of pesticides.

B. Distinction Between Agricultural and Nonagricultural Pesticides:

In 1978, Congress added a new requirement to FIFRA (Section 25(a)(1)) directing that regulations prescribed by the Administrator to carry out the Act shall take into account the difference in concept and usage between various classes of pesticides and differences in environmental risk, and the appropriate data for evaluating such risk, between agricultural and nonagricultural pesticides. This amendment extended an existing provision that required the Administrator to take into account the differences in concept and usage between various classes of pesticides, mandating that such a distinction be applied in prescribing and evaluating data for non-agricultural pesticides.

The Agency has not yet fully implemented this congressional directive. We believe that any FIFRA amendments in the Congress ought to provide specific language directing the EPA to separate out and utilize current administrative staff to specifically administer any regulations and guidelines which pertain to the non-agricultural portion of the pesticide industry.

We have also found that state legislators and some state regulatory agencies similarly are not taking into account the differences between agricultural and non-agricultural pesticides in proposing legislation and regulations. As a result, we often see proposed state legislation that would require, for example, that signs be posted before pesticides are applied in a residential building. In recent comments to one state, CSMA found it necessary to point out that the proposed regulations particularly failed to consider disinfectants and sanitizers. Therefore, we requested significant modifications to or withdrawal of the regulations until they could be rewritten to take into account the appropriate differences.

Under section 1703 of S. 2346, we specifically recommend that a new section 24(d) be added, mandating that states take into consideration the differences between agricultural and non-agricultural pesticides. In promulgating any regulations, policies, or protocols pertaining to the sale or use of pesticides within a state, the state should take into account the difference in concept and usage between various classes of pesticides and the differences in environmental risk and the appropriate data for evaluating such risk between agricultural and non-agricultural pesticides. In making a request for data submitted in support of a Federal registration, the state should take into account the difference in concept and usage between agricultural and non-agricultural pesticides.

With this provision, we believe some pressures for inappropriate state regulation would disappear because state regulators would have a federal mandate to consider the various types of pesticides when they propose appropriate regulations.

C. To Use Any Registered Pesticide In A Manner Inconsistent With Its Labeling

Under section 106 of S. 2346, we would recommend that a new Section 2 (ee)(5) be added to permit use of one pesticide in the formulation of another registered end-use product or to allow a registered product to be repacked into another end-use product unless prohibited specifically by the labeling. This provision was included in H.R. 5203 (97th Congress), and had widespread support in the House, as well as the Senate Committee on Agriculture, Nutrition and Forestry.

Another new Section 2 (ee)(6) could be added to specify that a misuse statement is not required on the label of all pesticides as is required by regulation. Currently, household disinfectants and sanitizers are required to use the statement "It is a violation of federal law to use this product in a manner inconsistent with its labeling." Such statements are not believable, and the users will simply refuse to believe they may be prosecuted if they do something other than that listed on the label. Under Section 2(ee), there should be an exemption for those "applying a household cleaning product containing a disinfectant or sanitizer active ingredient, in household or institutional cleaning uses.

D. Section 10. Protection Of Trade Secrets and Other Information

Under Title VIII of S. 2346, we would like to recommend two changes in Section 10 of FIFRA.

1) Freedom of Information Act (FOIA) Procedures (Section 804)

Under FOIA procedures, the EPA routinely releases the product label and internal EPA memos on the review of submitted data as soon as the product's registration is granted. The time lag between registration and sales can be quite lengthy, but the EPA does not recognize that giving this information to a competitor before sales begin amounts to disclosure of highly confidential marketing information, e.g., that a company intends to enter a specific market with a specific product.

Disclosures of any information on the intent to market a pesticide should commence at the start of sales, rather than at registration, unless the disclosure is specifically necessary to protect against a suspected unreasonable risk to health or the environment. Since all interested members of the public will have an opportunity to review this data prior to registration (under H.R. 4364), only business competitors will be denied access to the data.

2) Notification About Information Requested (Section 807)

Although the Administrator should notify the submitter of his intent to disclose trade secrets under Section 10(d)(3), disclosure of other data and information is not covered under FIFRA. A submitter should have the right to be advised that any of its data has been requested and that the agency plans to release it.

E. Section 3. Registration Of A Pesticide: Under Title II of S. 2346, we favor the following additions to FIFRA.

1) Section 3(c)(3).Time for Acting With Respect to Application (Section 203)

This section should be amended to include a time period in which an application should be reviewed and a determination made as to any shortcomings. We suggest a 90-day period in which the EPA must notify the registrant of a deficiency of the application. After the registrant has submitted adequate data to satisfy any deficiencies of information noted by the Administrator, the Administrator shall act upon the application within 180 days, unless he notifies the registrant in writing stating the reasons for the delay. If he fails to act after 360 days,the application is deemed approved.

2) Section 3(d)(1)(C). Restructuring of Classification System for "Restricted Use (Section 210)

Where the Administrator determines that the conditions of use of a pesticide indicate it should be classified in the restricted use category, he should be permitted more flexibility in addressing the matter than presently exists. Specifically, restricted use classification should not be automatically required where he finds that other measures, such as additional warnings and directions for use in the labeling, are equally effective.

F. Section 7(e). Information Requested

Although EPA maintains annually updated files of confidential data and information submitted under Section 7(e), the agency often requests this data again and again, for other purposes, because the files are not catalogued in a way that permits retrieval. For example, if EPA wants to know how many products contain sodium hypochlorite and in what amounts, it asks the registrants to duplicate data already in EPA's files. A new Section 7(e) contained in section 504 of S. 2346 would allow EPA to use the data in its files instead of asking registrants to continually duplicate them.

III. FIFRA and Patent-Term Restoration

Over the last several years, there have been numerous attempts to link FIFRA amendments to other federal legislative issues including patent-term restoration matters. We oppose any such linkage.

In the Fall of 1984, several environmental groups sought to link patent-term restoration and FIFRA amendments. In the House, H.R. 6034, the "Agricultural Patent Reform" legislation, introduced by Congressman Dan Glickman (D-KS) and Michael DeWine (R-OH), received a strong bipartisan vote in the Judiciary Committee on August 3, 1984. On the Senate side, Senators Strom Thurmond (R-SC) and Joe Biden (D-DE) introduced S. 2950, a bill identical to H.R. 6034. The "Agricultural Patent Reform" legislation dealt with FIFRA and pesticides, TSCA substances, and animal health products.

Congress, however, did not have time to act in 1984. Although Patent-Term Restoration legislation has again been introduced in the House and the Senate, there is still an effort to directly tie this issue to any proposed FIFRA amendment. Such a proposal might result in at least two committees claiming legislative jurisdiction, a process that could delay movement of FIFRA amendments, and raise new controversies.

There should not be any ties to FIFRA. Pesticide legislation should stand on its own merits. Jurisdiction should remain solely with the House and Senate Agricultural Committees.

IV. NEED FOR A BROADER, MORE COMPREHENSIVE ALTERNATIVE

Although we share some of the concerns in the NACA-CPR proposal, we believe that there should be a broader, more comprehensive alternative package of FIFRA amendments.

The NACA-CPR proposal is more narrowly focused on registration issues, and reflects the thoughts of only a portion of the pesticide industry. Many other groups -- agricultural and food groups, urban and rural pesticide user organizations, and other manufacturers -- have not had their concerns addressed in this document.

We need to pay more attention to the Environmental Protection Agency when it says that it has concerns about the rigid reregistration timetables, about processing 40,000 studies in 18 months, and about reviewing all registration data in 12 months. We should listen to the Agency when it says that they do not need an extensive new inert program or a new DDP for all inerts, or do not require a dynamic list that might result in the testing of more than 1,200 inerts. We should be concerned that the Agency cannot complete the cancellation process in 12 months.

We need to pay more attention to state officials who have asked for more and better certification and training programs, with more federal dollars to implement them. We should listen to their concerns about changing Sections 26 and 27 of FIFRA to allow for an annual programmatic review and for adequate time to initiate and commence an investigation into a complaint. We must devise a workable system to share data with the states.

We also believe that the concerns of the agricultural groups and pesticide users should be heard. We believe that the S. 2215 poses problems for minor uses, both agricultural and non-agricultural. For agricultural users, S. 2215 results in the relegation of minor uses to the bottom of the priorities and allows no exemptions for a reregistration fee. Under conditional registration, it specifically discriminates against minor use crops, requiring full data on new minor uses.

In addition, there are no provisions in the S. 2215 document to take into consideration minor uses of non-agricultural pesticides.

V. Conclusion

We would like to generally associate ourselves with the testimony offered by other members of the FIFRA Coalition. This broad-based group of organizations representing urban and rural pesticide user groups, agricultural user groups, farm groups, and commodity producers as well as manufacturers reflects different concerns about FIFRA.

We do, however, share a common goal that all pesticides are safe and effective for their intended uses and that they do not pose unreasonable risks to man and his environment. Many of the concerns we have noted in our full text today impose an unnecessary economic burden upon our industry and will deprive consumers of safe and effective pesticides needed to control pests which disrupt our economy and reduce the quality of our lives.

If we are to seek a four- or five-year FIFRA reauthorization -- we need to address FIFRA in the broadest possible terms, attempting to reach out to the concerns of all groups and organizations. We need to offer constructive alternatives that enhance, not impede, the legislative process. We need to build upon, not dilute, the momentum resulting from the NACA-CPR agreement. We need to address issues that concern farmers, users, small businesses, and other manufacturers. We need to hear the thoughts of federal and state officials who must interpret and enforce the law.

We respectfully ask your support in seeking a broader, more comprehensive alternative FIFRA package that represents a broad compromise and establishes a consensus among many concerned groups and organizations. Specifically, we urge this committee to support S. 2346.

We at CSMA are committed to working with the committee to help resolve these important concerns and to improve the prospects for passing FIFRA legislation this year.

STATEMENT OF HARVEY S. GOLD, EXECUTIVE VICE PRESIDENT NATIONAL PEST CONTROL ASSOCIATION

Mr. Chairman and members of the Committee:

INTRODUCTION

My name is Harvey S. Gold. I am the Executive Vice President of the National Pest Control Association, the national membership association of structural, general household, industrial, and institutional pest control companies in the United States.

On behalf of the National Pest Control Association and its almost 2,400 member firms, I thank the Committee for this opportunity to present our experience as pesticide users in working with pesticides under the provisions of the current FIFRA[1], and to share our comments and recommendations on the proposals for amendments to this Act, as presented in S. 2346 introduced by Senator Helms and S. 2215 introduced by Senator Lugar.

The members of the National Pest Control Association are those service companies in the nation's business that work to protect the public health, our food supply and our building structures from pest infestations and disease vectors carried by these pests. The National Pest Control Association's technical competence in research, education and training in the use of pesticides and in the production of a wide variety of educational and training materials has international recognition. This is supported by membership from 43 foreign countries representing about 138 foreign pest control companies in the National Pest Control Association. Our educational materials are referenced and suggested by both federal and state regulatory agencies for the training of pest control operators on how to ensure the safe and effective control of pests -- from cockroaches and termites to vertebrates such as rats and birds.

Pests are controlled by use of integrated pest management programs that include sanitation, education, sometimes exclusion and relocation of pests, and with the use of pesticides where needed.

The members of this industry depend primarily upon their knowledge of pest biology and behavior and their experience with a diversity of control methods appropriate for the site rather than depend exclusively upon pesticides that are classified by EPA for either restricted use or for general use. It is important to note that currently over 95% of the pesticides used in our industry are in the non-restricted or general use category and the same pesticides that are approved by EPA for purchase and use by the general public.

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[1] The Federal Insecticide, Fungicide, and Rodenticide Act (as Amended 1978).

THE EXISTING FIFRA

At the outset, I would like to say that the National Pest Control Association strongly supported the initial FIFRA legislation which gave the Environmental Protection Agency the authority to regulate the use of pesticides. We have actively supported EPA approved programs of certification of persons who apply or supervise technicians in applying pesticides classified by EPA and the states for "restricted use." It is, and has been, the policy of the National Pest Control Association and its membership to use only those pesticides that are registered by the responsible authorities of state and federal governments and to apply them in the manner described in the manufacturer's registered label and recommended by professional authorities in our field. We are pleased to note that compliance with the label instructions has resulted, year after year, in a high rate of safety, especially in view of the total number of millions of pesticide applications made each year.

THE PROPOSED AMENDMENTS IN S. 2346

S. 2346 is the result of negotiations of over 40 pesticide manufacturer, distributer, and user groups including the National Pest Control Association. This group is identified as the FIFRA Coalition. We favor the proposals in S. 2346 since they have been developed by a broader and more comprehensive base of associations and interests that are concerned and impacted by FIFRA than does S. 2215 which is concerned with manufacture or registrant concerns exclusively. S. 2215 was developed cooperatively by a coalition of environmentalists jointly with one trade association, the National Agricultural Chemicals Association (NACA), which represents primarily the larger pesticide manufacturing interests.

I have selected for comment those proposals in S. 2346 that directly affect our industry's commercial pesticide users. These are the provisions on: 1. Certification, Training and Record Keeping, 2. Label Use Protection, 3. State Primacy, and 4. Public Right-to-know. Our comments on these provisions are as follows:

CERTIFICATION, TRAINING AND RECORD KEEPING

The changes that are proposed (Title III) provide for expanded and updated training requirements for both certified applicators and non-certified commercial applicators who work under supervision of certified applicators. Specifically, all mixers, loaders and applicators, except private homeowners, will be required to receive and verify to the state lead agency that education and training for safe pesticide use, handling and pest control has been received. This will provide a basic education and training program that will be used in conjunction with the existing program for certified applicators. Thus the proposed Title III of S. 2346 strengthens the education and training requirements of the existing law with the following changes:

1. Sets minimum passing percent on applicator test. A 70% passing grade is specified on training requirements that are more stringent than those under the existing law.

2. Requires field experience not to exceed two years for eligibility for certification as a commercial applicator. The existing law requires only a passing grade for certification. By adding on the job experience in relevant application specialty categories, training is made more practical and is expanded to assure demonstrated competence on the job.

3. Requires verification to the state agency of successful completion of training of the commercial applicator who works under supervision applying any (both restricted and non-restricted) pesticide. By registering non-certified applicators with the state lead agency the state will have the capability of identifying and monitoring the violation history of all commercial applicators in the state.

4. Requires verification by the state of the credentials of those providing the training for all pesticide applicators, both private and commercial. The existing law is strengthened by specifying that the state lead agency establish competency requirements for separate specialty categories of pesticide trainers.

5. Requires refresher training at least every five years of certified and non-certified (under supervision) applicators. The frequency of refresher training needed depends on the availability of new knowledge and experience. This provision specifies a maximum period for this update training.

6. In addition, certification of enforcement personnel is mandated to assure that enforcement personnel are competent in the category where they have enforcement responsibility.

Record keeping by pesticide dealers of pesticide sales to private and commercial applicators and access to these records by qualified persons is designed to allow federal and state authorities to monitor quantities of pesticides sold and used and to identify where and by whom the pesticides are being used, for commercial as well as private (farm) applicators. Retail vendors of pesticides to homeowners are currently excluded from this record keeping process. Title IX of S. 2346 strengthens the existing law by setting additional record keeping requirements for commercial applicators and specifying the arrangements for access to these records. These provisions in S. 2346 concerned with record keeping by commercial pesticide applicators cover all applications and provide access to these records by qualified persons in order to document pesticide use according to the law for at least two years. Any longer period of time would be extremely burdensome for the many small businesses that make up the commercial pesticide user industry.

LABEL USE PROTECTION

All parties are interested in assuring compliance with the pesticide label by pesticide users. It is our experience that the vast majority of commercial pest control operators are faithfully following EPA approved label use rules. We need to reward those that are doing so and make the penalties sufficient to deter deliberate misuse. The pesticide label remains the foremost vehicle for informing and warning the pesticide user, and determining whether the pesticide was applied correctly. Efforts to improve the label compliance should cover both penalty and reward. A provision has been added under Title IX concerned with unlawful acts in S. 2346 to define the liability of those who can prove that they obeyed the pesticide label. This section adds an amendment to establish that the applicator exercised the proper standard of care if the applicator can prove compliance with the FIFRA label.

Under the Penalties section of the proposed amendments we support doubling the existing FIFRA penalties.

STATE PESTICIDE ENFORCEMENT PRIMACY

During the 1980s, political subdivisions in different states such as cities, counties or townships, have attempted to exercise the same pesticide regulatory authority as the state. Such attempts to usurp the authority of the state are contrary to the legislative history of FIFRA. We support the adoption in Section 24 (a) of the existing law, of an amendment to solve the growing problem of local pesticide regulation. We strongly support the amendment to this section with the provision in S. 2346 that would read "a state but no political subdivision of the state, may regulate the sale and use of any federally registered pesticide ..." This implements the original Congressional intent which has been supported in testimony in 1972 and 1978 in FIFRA oversight hearings.

The problem is that local ordinances are creating unnecessary confusion and increasing the complexity of different rules in various communities for pesticide use. For example, if every community adopted its own differing rules for pesticide use, it would be near impossible for the pesticide service personnel to avoid confusion. It is more important for the applicator to concentrate on the safe use of pesticides than a multitude of different local use rules. It also is costly to the business community and to the public to deal with a multiplicity of regulations. It distracts applicators from providing professional pest control services.

This clarification would not pose a threat to the needs of local jurisdictions of government. If a town or county wished to have certain pesticide use eliminated completely or between certain hours they need only to petition the state regulatory agency. The decision to approve should be forthcoming if, for example, it doesn't endanger the state's ability to control disease vectors like mosquitos or rodents or otherwise pose a health threat to the entire state population.

Althouth it will require the state approval of any local pesticide regulatory action, agreements can be reached by states with localities for flexibility, depending upon the needs of the locality, as for example, in notifying sensitive individuals of future pesticide applications on a community-wide basis. The intent is not to deny local jurisdictions but to provide an orderly and sound basis for pesticide use rules.

PUBLIC RIGHT TO KNOW

NPCA fully supports the concept of sharing pesticide information with the public. We believe that the state pesticide regulatory agency, together with the distributors, rather than EPA, would provide a more efficient way of collecting and distributing information about pesticides. S. 2346 has provisions (Title II) that require the use of Material Safety Data Sheets (MSDS) that are required already under the Occupational Safety and Health Act (OSHA). This provision in S. 2346 would require such information on pesticides be provided by the registrant to the states for distribution to the public upon request. Rather than requesting each registrant to create a new document that duplicates the MSDS, this section requires the registrant to submit the MSDS to the state agency for distribution to the public. It provides two sources for distribution of these fact sheets to the public, the state and the registrant. This would be much more effective than requiring EPA to collect and distribute information about pesticides to the public. For example, if each of the 65,000 EPA registered products contained a three page fact sheet the EPA would have the unnecessary administrative burden to collect, store, categorize, retrieve and dispense nearly 200,000 pages to the general public. This would amount to millions of pages of paper. We believe at a time of budget cutting, there is no need to impose this additional paperwork and financial burden on the agency's resources.

We agree completely with the provisions in S. 2346 that places this responsibility not only on the registrants but also for the state in distributing the fact sheets to the public upon request.

CONCLUSION AND RECOMMENDATIONS

Mr. Chairman, we recommend your adoption of these proposd FIFRA amendments in S. 2346.

I would like to thank you for this opportunity to present our experience on the use of pesticides under the existing FIFRA and to share with the committee our recommendations for improving the effectiveness of this very important regulatory authority.

I will be pleased to respond to any questions you may have on our testimony today.

Thank you.

STATEMENT OF EARLE K. BORMAN, JR., STERLING DRUG INC.

Sterling Drug Inc. (Sterling) appreciates the opportunity to present comments on the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) amendments under consideration by the Committee. Sterling has a keen interest in these amendments. The company currently has 138 products registered under FIFRA. This number does not include any of the big agrichemical pesticides discussed in testimony before the Committee in the April 22 and 30 hearings. Instead, these products include Lysol™ Brand Disinfectant Spray and home cleaning agents, d-Con rat and mice control products, hospital disinfectants and sanitizers, and flea and tick sprays.

Sterling's business is primarily formulation. It buys active ingredients and formulates them into other pesticide products. With respect to FIFRA, that means Sterling does not have to develop or submit to EPA toxicity data on the registered active ingredients purchased from other manufacturers. This responsibility lies with the registrant of the active ingredient itself. However, it would be a mistake to think, as many apparently do, that the provisions of S. 2215 do not affect formulators of domestic application products. They do -- and very significantly, particularly the provisions on reregistration, regulation of inert ingredients, and preregistration access to data.

For example, many of the registered active ingredients used by Sterling are antimicrobial agents. As EPA has recognized in efforts to develop a comprehensive reregistration strategy for antimicrobials -- the disinfectants, sanitizers and sterilizers which kill bacteria and disease-causing germs -- the economics of this industry are very different from those of the companies which comprise the National Agricultural Chemicals Association (NACA), the industry group which negotiated the provisions of S. 2215. One key difference is that approximately 286 of these active ingredients account for only 8% of the market. Further, the toxicity of domestic application/antimicrobial products is far less in comparison with major agricultural use products. These differences, in both the inherent toxicity of the products and the industry structure, must be recognized or many antimicrobial products may simply disappear from the market with a concomitant impact on formulators who use these active ingredients and consumers who use the ultimate formulated product. This is not, we assume, the desired effect of S. 2215 but could well be the result of the inflexible approach to reregistration mandated by that bill.

In addition, S. 2215 simply does not address key issues of concern to formulators of domestic application products like Sterling. From the formulator's perspective there are three key problems which must be addressed in any reauthorization of FIFRA. These are (1) the fact that it takes too long to obtain a registration; (2) EPA's failure, to date, sufficiently to distinguish requirements for the regulation of domestic application/antimicrobial products from those for agrichemical products; and (3) the proliferation of state regulation of federally registered domestic application/antimicrobial products. S. 2346 represents much more comprehensive package of amendments on the issues of concern to the formulator industry, but also needs to be modified in certain respects.

I. THE DOMESTIC APPLICATION AND ANTIMICROBIAL PRODUCTS DISTINCTION

The goals outlined above could be achieved through a series of amendments which distinguish the regulation of domestic application/antimicrobial agent products from the regulation of big agrichemical food and feed pesticide applications. The first of these amendments would add to FIFRA Section 2 a definition of the terms "domestic application" and "antimicrobial agents". The definition of "domestic application", as derived from EPA's current regulatory definition of the same term at 40 C.F.R. § 162.3(m), would read as follows:

> The term "domestic application" means application of a pesticide directly to humans or pets, or application of a pesticide in, on or around all structures, vehicles or areas associated with the household or home life, patient care areas of health-related institutions, or areas where children spend time, including but not limited to:
>
> (1) gardens, non-commercial greenhouses, yards, patios, houses, pleasure marine craft, mobile homes, campers and recreational vehicles, non-commercial camp sites, home swimming pools and kennels;
> (2) articles, objects, devices or surfaces handled or contacted by humans or pets in all structures, vehicles or areas listed above;
> (3) patient care areas of nursing homes, mental institutions, hospitals and convalescent homes; and
> (4) lounging and recreational areas of preschools, nurseries and day camps.

The definition of "antimicrobial agents", as derived from EPA's current regulatory definition at 40 C.F.R. § 162.3(ff)(2), incorporated in part in S. 2346, Section 1601, would read as follows:

> The term "antimicrobial agents" includes substances or mixtures of substances intended for inhibiting the growth of, or destroying any bacteria, fungi pathogenic to man and other animals, or viruses and existing in any environment except those subject to the provisions of the Federal Food, Drug and Cosmetic Act. Antimicrobial agents include, but are not limited to,
>
> (a) disinfectants intended to destroy or irreversibly inactivate infectious or other undesirable bacteria, pathogenic fungi, or viruses on surfaces or inanimate objects;
> (b) sanitizers intended to reduce the number of living bacteria or viable virus particles on inanimate surfaces, in water, or in air;
> (c) bacteriostats intended to inhibit the growth of bacteria in the presence of moisture;
> (d) sterilizers intended to destroy viruses and all living bacteria, fungi and their spores on inanimate surfaces;
> (e) fungicides and fungistats intended

to inhibit the growth of, or destroy fungi (including yeasts), pathogenic to man or other animals on inanimate surfaces; and

(f) commodity preservatives and protectants intended to inhibit the growth of, or destroy bacteria in or on raw materials (such as adhesives and plastics) used in manufacturing, or manufactured products (such as fuel, textiles, lubricants, and paints).'

These definitions can serve as the basis for a series of amendments which remove domestic application/antimicrobial agent products from the agricultural chemical orientation of S. 2215. Instead, this product group should be subject to regulation under a system which preserves and expands EPA's current discretion to regulate domestic application/antimicrobial agent products in a manner fully consistent with the "unreasonable risk" orientation of the FIFRA statute.

II. REREGISTRATION AND FEES

The expense and lock-step reregistration of all 600 active ingredients not reregistered since 1978 as proposed in both S. 2215 and S. 2346 will likely have an unanticipated and undesirable impact on the availability of domestic application and antimicrobial products. This problem is exacerbated by the arbitrary reregistration fees imposed by S. 2215. From the perspective of a formulator, EPA's current reregistration scheme -- on which both the provisions of S. 2215 and S. 2346 are based -- is far better, at least for the antimicrobial active ingredients which constitute the majority of domestic application products. However, even that scheme could be improved upon by establishing a threshold of concern which must be met prior to required reregistration of these products.

A. Reregistration Scheme.

The simultaneous reregistration scheme, with its estimated $70-100 million price tag, was drafted with the reregistration of agrichemicals used in major food and feed applications as a model. EPA, the regulated agrichemical businesses and some environmentalists have a clear idea of the appropriate reregistration procedures for these chemicals because they have now acquired a great deal of experience with these products. In fact, as several witnesses including EPA testified last week, EPA has completed registration standards for many food use chemicals and has issued a data call-in on essential health effects for all of these. EPA is not nearly as far along with the reregistration of antimicrobial agents, many of which fall near the bottom, in category 39, of EPA's original priority ranking of 48 clusters of active ingredients.

What is different about this group of domestic application and antimicrobial products, and why does Sterling, as a formulator, care about what happens to them? First, according to EPA there are roughly 300 active ingredients contained in some 14,000 products. Ninety-two percent (92%) of the total antimicrobial production (which is approximately 37% of the total annual production of pesticides) is accounted for by just 14 active ingredients. Many of the remaining 286 have an annual production of less than 10,000 pounds. EPA has typically issued registrations for antimicrobial products based upon acute toxicity studies to support the safety of use, on the theory that exposure to these chemicals is short-term and in low concentrations.

A threshold reregistration issue for these active ingredients as a group is whether this assessment of exposure is correct. To answer that question, and therefore determine whether additional subchronic and chronic testing is necessary, requires the development of exposure data by the industry and/or EPA based on use patterns (i.e., mop application products, spray disinfectants and mold killers, etc.). EPA is discussing with industry how to develop this data in a cost-effective way that will not drive the 286 active ingredients off the market, a result undesirable from the perspective of EPA and the public. Once the exposure data has been generated, EPA believes that it may be able to devise some additional groupings of antimicrobial actives to reduce the costs of any additional subchronic or chronic testing that may be required.

This reregistration scenario is different from reregistration for agrichemical active ingredients. It illustrates the great need for flexibility on the part of EPA to tailor reregistration requirements to the unreasonable risk determination EPA must make. It also illustrates the folly of blithely assuming that the same steps will be followed for the reregistration of each active ingredient, notwithstanding the myriad profiles of the many different active ingredients.

As a formulator, this issue is of great concern to Sterling, which, like all formulators of these products, purchases a large number of antimicrobial active ingredients. If these actives are forced off the market by an inflexible reregistration scheme which does not rationally account for the low toxicity of the products, Sterling will (1) be forced to reformulate products as a result of loss of registration, (2) assume the registration itself, an option which would probably be rejected as not economically justifiable, particularly for hospital sanitizers, disinfectants and sterilants, or (3) if reformulation is not possible, drop the product. While Sterling obviously has a strong corporate interest in maintaining its current product line, the public benefit of these products -- which do kill disease-causing germs -- should not lightly be discounted.

In sum, EPA is doing a reasonably good job on reregistration of these products now. However, the automatic reregistration is not appropriate for domestic application and antimicrobial products per se, many of which, like Lysol™ Brand Disinfectant, have been in safe usage for generations. Congress should adopt a threshold test as a predicate for the required reregistration of these products based upon a hazard evaluation which considers level of toxicological concern and potential risk. In order to develop more accurate data on the risks posed by such products as disinfectants and sanitizers, Congress might consider incorporating a requirement in the statute that formulators of these products maintain records of allegations of consumer injury similar to the current requirement of Section 8(c) of the Toxic Substances Control Act.

B. Fees.

S. 2215 requires EPA to levy a reregistration fee to fund, at least partially, the massive cost of its proposed program to reregister all active ingredients simultaneously. For non-food use active ingredients, these fees are a minimum of $75,000 per active. There is no provision whatever for a waiver of this fee.

These fees, as applied to antimicrobial active ingredients, and especially those actives with less than 10,000 pounds production, could well force these actives off the market. This is particularly unfair to the small registrant. First, the cost of administration of statutes designed to protect the public health and welfare, like FIFRA, is traditionally and correctly borne by the public. Second, it is completely inappropriate, not to mention unfair, to charge producers of products now on the market to fund FIFRA review necessitated by a change in regulatory data requirements when there is no new registration application for a new product. Third, the dollar figures for non-food use active ingredients in S. 2215 have no factual basis whatsoever. They apparently "seemed reasonable" to the developers of S. 2215 with no significant thought or data base concerning either their proportional validity or the implications for the industry affected.

If there is to be any reregistration fee assessed for domestic application and antimicrobial active ingredients, a fee which Sterling vigorously opposes, it must (1) bear some proportional relationship to the true data needs for the particular ingredient, and (2) be maintained in a separate, not a revolving, fund. Finally, EPA must have the discretion to waive or reduce any such fee in its entirety where it would pose an undue economic burden or would be unwarranted based on the reregistration scenario selected for a group of active ingredients.

III. INERT INGREDIENTS

The inert ingredient regulatory systems proposed in both S. 2215 and S. 2346 present serious problems from the formulator's perspective, although S. 2346 represents a great improvement over S. 2215. Fundamentally, it must be remembered that inert ingredients are those portions of pesticidal products which are not pesticidally active. Formulators' domestic application/antimicrobial products contain, proportionally, a much greater percentage of inert ingredients than do agrichemical pesticides. For example, a house and garden pesticide will rarely contain more than 2.0% active ingredient, as compared to 20-90% active ingredient contained in agrichemical products. The remaining 90% of the domestic application and antimicrobial products consists of inert ingredients, the identities of which are closely guarded confidential and proprietary trade secrets.

EPA estimates that approximately 1,200 inerts exist, ranging from methylene chloride to cookie crumbs. EPA has required the development of data on these inert ingredients under the current authority of FIFRA Sections 3(c)(1)(D) and (c)(2)(D) and has adopted a strategy for regulation, the objectives of which are:

(1) to identify new and old pesticide products that contain toxic inert ingredients, and to develop a regulatory strategy to minimize public health and environmental risks;
(2) to encourage removal of toxic inert ingredients from pesticide products where risks are not justified;
(3) to create incentives to substitute inert ingredients that present less risk;
(4) to establish testing programs and requirements to reduce uncertainties about the toxic effects of and exposure to inert ingredients;
(5) to make effective use of Agency resources; and
(6) to allow public awareness of existing toxic or potentially toxic inert ingredients in pesticide products so appropriate precautions may be taken in prod-

uct use.

"Strategy for Regulation of Inert Ingredients Used in Pesticide Products", April 16, 1986 EPA draft.

The philosophy of this strategy is that each inert should be regulated based on its level of toxicological concern and potential risk. A high level of concern will lead to stringent regulation of the inert, including a requirement that the identity of the inert be disclosed on the label of the product.

This is a proportionately reasonable and well-focused solution to the increased concerns about inert ingredients in pesticides. It is significantly better than adding an extraordinarily resource intensive and cumbersome regulatory program mandating review and study of all ingredients in widespread use as proposed in S. 2215. Sterling fully supports the position taken by EPA before this Committee and by the Audobon Society and the Environmental Defense Fund in testimony in the House that it is completely unnecessary to codify this program in the statute.

Sterling also supports amendment of the statutory definition of ingredient statement to authorize EPA to require identification of an inert on the label after the inert has been determined to pose a hazard based on its level of toxicological concern and potential risk. S. 2346. One caveat to be noted is that Sterling does not support the language in H.R. 2482 which authorizes EPA to require disclosure of the percentage of the inert ingredient in addition to its identity. This information directly increases the ease with which a competitor can reverse engineer the formula of the product and is tantamount to giving away valuable business assets.

IV. PREREGISTRATION ACCESS TO DATA

The domestic application/antimicrobial markets are highly competitive. Preregistration access to data on new active ingredients intended for use in these markets greatly increases the possibility that confidential business information will fall into the hands of competitors. The safeguards against such disclosure provided in the pending legislation are inadequate. Access is authorized on the basis of what amounts to a business card indicating the applicant is not affiliated with a competitor and a certification to that effect. While false certification is made a crime under 18 U.S.C. § 1001, disclosure of information so acquired is not punishable under S. 2215, for example, unless made with intent to defraud in the case of formula disclosure or done "knowingly". This is not adequate protection -- negligent or unwitting disclosure of information secured through preregistration access is just as harmful to a company's competitive position as willful disclosure. It must, in addition, be recognized that this type of crime will be very difficult to prove since it will involve complex scientific issues, not to mention the fact that U.S. Attorneys already have full dockets. As a result, such cases are unlikely to be prosecuted.

Moreover, the rationale for the provision, as clearly expressed in Mr. Myerhoff's testimony last week, is to permit environmental group supervision of EPA's implementation of registration. This is completely unnecessary in view of the newly revised registration criteria. Moreover, the role Mr. Myerhoff envisions is precisely the role of government and EPA itself.

V. EXPORT OF PESTICIDES

Individual national regulatory requirements for pesticides are proliferating on the international scene. Many countries, for example, now have their own labeling requirements in addition to packaging or preparation requirements. In many situations, some of the information required on the label of products produced for export, such as the EPA establishment number, is entirely superfluous in the foreign country. Conversely, additional information appropriate to the importing country may be necessary -- e.g., the health authority to be consulted. Therefore, Section 17(a) should be amended to provide, as an alternative to the labeling requirements that apply to such products currently, that the product may be labeled, as well as prepared and packaged as permitted under the current law, according to the specifications of the foreign importing country. This could be accomplished by deleting the period at the end of line 11, p. 59 of S. 2215 and adding the phrase "unless such pesticides and devices and active ingredients used in producing pesticides are labeled according to the specifications of the country of importation."

Sterling supports EPA's position that it is inappropriate to expand the notification obligations of exporters or EPA beyond the requirements of the existing statute. EPA correctly notes that it would be far more appropriate in the international community to follow the uniform notification scheme for banned and severely restricted chemicals which has been developed under the auspices of the U.N. Environment Programme.

VI. COORDINATION WITH STATE REGULATION OF THE SALE AND USE OF PESTICIDES

Sterling supports the proposals of S. 2346 to limit state authority to regulate pesticides registered under FIFRA. However, with respect to domestic application and antimicrobial products, the proposed amendments do not go far enough. State limitations and restrictions on such products which are manufactured for a national market can create an undue burden on interstate commerce. State authority to regulate these products should give way to the Federal Government's regulatory decision under FIFRA unless additional state regulation can be justified by compelling local conditions. This could be accomplished by adding language from Section 18(c) of the Occupational Safety and Health Act, where a related concern was resolved as to state OSHA-type regulations which apply to products (i.e., objects moving in interstate commerce) which are stricter than the federal standard. Thus, the federal regulation would prevail unless the state standard can meet two tests: (1) it is required by compelling local conditions; and (2) it does not unduly burden interstate commerce.

This change could be effected by the addition of the following underscored language to existing FIFRA Section 24(a):

> Except with respect to federally registered pesticides for domestic application or for antimicrobial products, a state may regulate the sale or use of any federally registered pesticide or device in the state, but only if and to the extent the regulation does not permit any sale or use prohibited by this Act. A state may regulate the sale or use of a federally registered pesticide for domestic application and federally registered antimicrobial products only if such regulation is required by compelling local conditions and does not unduly burden interstate commerce.

VII. OTHER ISSUES

1. Conditional Registration

Sterling supports current law on this provision which permits conditional registrations of new uses and new active ingredients where a finding of no significant increase in unreasonable risk can be made. This authority has been used sparingly by EPA and is appropriate in some cases. The proposal in S. 2215 to eliminate EPA's authority to issue conditional registration of new uses unless all data have been supplied removes important flexibility. Conditioning this authority on the submission of satisfactory data, coupled with the required unreasonable risk finding, is preferable. Similarly, the proposed amendment in both S. 2215 and S. 2346 eliminates EPA's authority to issue a conditional registration for a new active ingredient pending development of a complete data set -- even where such a conditional registration might be overwhelmingly in the public interest. To tie the Agency's hands in this way is simply poor public policy.

2. Public Right-To-Know

Sterling supports the right-to-know amendment in S. 2215 requiring fact sheets summarizing relevant health, safety and environmental data for pesticide active ingredients. For the reasons identified in Section III above, fact sheets for inerts should be required after EPA determines, based upon a risk assessment, that regulation of the inert under FIFRA is necessary.

The provisions of S. 2346 which require Material Safety Data Sheets (MSDSs) be maintained for all registrations and add the current OSHA Hazard Communication Standard requirements for MSDSs to the FIFRA statute should be rejected as redundant.

3. Data Disclosure to the States

Those states, such as California, which feel a need for data provided to EPA under FIFRA, generally require this data to be submitted to them as a matter of state law. Any issues respecting confidential treatment to be accorded such data are sorted out between the registrant and the state under the respective state laws. Sterling is very concerned about a blanket authorization to EPA to disclose data, based upon EPA's determination that state law provides confidential business information the same protection as federal law. With all due respect to EPA, this is not an area in which EPA has special expertise. At a minimum, any such provision should include pre-notification to the registrant of the proposed disclosure with an opportunity to make an assessment of state law and seek judicial intervention if necessary.

4. Cancellation Procedures

Sterling supports the provisions of S. 2346 with respect to cancellation procedures. Section 3(c)(8), as implemented through EPA's new criteria for initiation of Special Review which balance evidence of both adverse effect and magnitude and scope of exposure of humans, should not be changed, especially in favor of a risk-only trigger as proposed in H.R. 4364. As characterized by Dr. Moore, this proposal is a step backwards in streamlining Special Review because it means Agency resources could be wasted reviewing pesticides which present a risk, but for which there is no significant exposure of any concern. In addition, Sterling sees no reason to add a provision for an adjudicatory hearing following Special Review, but supports retention of an adjudicatory hearing for cancellation as a necessary protection of the registrant's rights.

5. False or Invalid Data

Sterling supports the provisions of S. 2346 which authorize the cancellation of a registration based upon false or invalid data where EPA and the registrant have been unable to agree upon a plan for replacement studies and no commitment to submit replacement studies has been secured from the active ingredient registrant, the end-use pesticide registrant, or users. Sterling also fully supports the amendments authorizing cancellation for willfully submitted false data. However, Sterling opposes the provision of H.R. 2482, the EPA bill introduced last year, which would also authorize cancellation of registration based on inaccurate or misleading data. These terms are inherently vague, subject to broad definition, and as such should not be used in the statute to trigger cancellation.

6. Inspection of Laboratories

Sterling supports the amendment to authorize inspection of laboratories generally but prefers the broader language of S. 2346, which authorizes inspection of any pesticide testing facility rather than simply facilities providing data in support of an experimental use permit or registration. One amendment to this provision which should be added is a requirement that the EPA-authorized representative conducting the inspection be technically qualified to do so. The legislative history of this provision should in turn reflect the fact that the term technically qualified means technically qualified for the job the inspector is sent to do -- *i.e.*, verification of the accuracy of the data submitted. This could be accomplished by inserting the following language after line 25 on p. 66 of H.R. 4513:

> An authorized representative for purposes of any pesticide testing facility shall be technically qualified to verify the accuracy of the data being submitted by the testing facility.

7. Employee Protection

Sterling supports current law on this issue.

8. Label Use Protection

Sterling supports the concept of label use protection, as a reasonable limitation on liability of the individual using the product as directed by the label, in view of the close regulatory scrutiny of the contents of that label.

9. Certification, Training and Recordkeeping

Sterling does not produce restricted use products which would be subject to regulation under the proposed provisions in S. 2346. However, from a public policy perspective, these amendments appear to be very important to protect the public against improper application of restricted use pesticides, such as chlordane and other termiticides about which there has been so much controversy.

10. Registration

The registration of new pesticides is EPA's primary function under FIFRA. The amendments in S. 2215 either have lost sight of this fact or must be interpreted as saying registration is fine as is. This is definitely not the case. From the perspective of a pesticide formulator of domestic application/antimicrobial products, it takes too long to get an EPA registration for a domestic application/antimicrobial product, the active ingredient of which has already been approved, or for a domestic application/antimicrobial product with a new active ingredient. In this regard the proposed amendments to Section 3(c)(2)(A) in S. 2346 to require expedition of the process are desirable in concept, although the automatic registration as a consequence of Agency inaction is not. EPA should be directed to expedite the registration process for domestic application/antimicrobial products.

11. Collection, Dissemination and Utilization of Data

Sterling supports the provision in S. 2346 to require EPA to establish and coordinate an efficient system for the collection, dissemination and use of data submitted to EPA under FIFRA. The Agency's track record with respect to data management is poor and formulators often find themselves faced with multiple requests for data already submitted or charges of failure to submit data which arise from the fact that once submitted, the data has been misplaced at EPA.

STATEMENT OF ROBERT M. RUSSELL, ORKIN PEST CONTROL, ATLANTA, GEORGIA

I am Robert M. Russell of Orkin Pest Control, a division of Rollings, Inc. Orkin is the world's largest in structural pest control. We operate in 43 states in this country; we employ 5,000 people; we serve over a million customers. We offer these comments for our company, for all other conscientious users of pesticides, and on behalf of our employees and customers.

Structural pest control, as opposed to agricultural pest control, is a service industry. Our service is conducted in both commercial structures and in residential buildings. We help protect the food, the fiber, the structures, and even the health of our nation. To render this service, and as with most service industries, we send a trained technician to the customers' premises. As we are dealing with household insects and wood-destroying insects and organisms, our control procedures are of necessity carried out inside the homes and buildings of our customers.

Control of pests necessitates the use of pesticides. These chemical and botanical substances are safe to both our technicians and to others who might be exposed when label instructions are followed. Application is governed by both Federal and State laws.

We are glad that this Committee is examining the issue of safe pesticide use in the context of FIFRA.

We would like to indicate to this Committee the high efficiency and safety of our structural pest control industry.

The latest national report from The Council of Better Business Bureaus, Inc., published for 1984 shows the quality position of our industry. Of 384,700 complaints received from all type of companies nationwide, only 1,801 concerned structural pest control companies. The fact that the pest control industry ranked only 38th in the number of complaints, with a percent of the total of 0.47% is an outstanding achievement.

We also wish to remind of the EPA publication, "Analysis of the Risks and Benefits of Seven Chemicals Used for Subterranean Termite Control" which stated in Chapter VI, Pages 1 and 2: "At this time in assessing the risks and benefits associated with the total national use of the termiticides based on available data, and considering the lack of data outlined above, the Agency finds that the benefits from the use of the currently registered termiticide products outweigh the potential risks." Accordingly, these pesticides are still registered by EPA. Moreover, most of the pesticides used by our industry are categorized as a general-use rather than restricted-use pesticides.

We would like to also quote from a recent EPA Task Force on "Certification and Training." The report of this group, released August 30, 1985, stated "The pesticide applicator training and certification programs have resulted in improved human health and environmental protection and have permitted the continued use of a variety of beneficial pesticides."

These authoritative and unbiased reports speak very well for the efficiency of our structural pest control industry.

There is also some very encouraging data being published relative to the safety of the pesticides used by the structural pest control industry.

A recent study by the California Department of Food and Agriculture, Worker Health and Safety Unit, showed that only 3% of pesticide accidents were caused by the structural pest control industry. This study covered the year 1982.

In another California study, the Poison Control Center of Los Angeles, during the period January through April 1983, received

24,000 telephone inquiries. Of the 1,182 pesticide related calls, 97% concerned pesticides purchased by consumers. Only 38, or 3%, related to pesticides applied by pest control operators and none of these could be classified as poisonings.

These studies strongly indicate that accidents resulting from trained applicator misuse are infrequent and a small percent of the total pesticide incidents.

We next would like to comment on the general good health in this country and the steady improvement in life expectancy. From the "National Center for Health Statistics, Life Expectancy Data for 1981, Section 6, Life Tables," we quote:

LIFE EXPECTANCY FOR ALL RACES, BOTH SEXES, ESTIMATED AVERAGE

1950	68.2 Years of Age
1960	69.7 Years of Age
1970	70.8 Years of Age
1980	74.2 Years of Age

During this time, use of pesticides was also increasing. Based on figures published in 1978 by the United States International Trade Commission, the amount of pesticides applied during the period 1965 through 1975 increased significantly:

1965	750,000,000 Pounds of Pesticide
1970	825,000,000 Pounds of Pesticide
1975	1,225,000,000 Pounds of Pesticide

We believe both trends, longer life expectancy and greater use of pesticides are continuing.

Thus, though more people are exposed to more pesticides, it in no way seems to affect the health of our nation, for general good health and life expectancy continue to increase.

I also wish to address the issue of the application of restricted-use pesticides by or under the direct supervision of a certified applicator. This is now required by Federal law and rightly so for those supervisors of a work unit such as a structural pest control branch office. The existing law acknowledges the structure of our industry by defining "under the direct supervision" of a certified applicator to mean that the certified applicator must be available but not physically present (Section 2(e)(4) of FIFRA).

There are some who now advocate testing or certification for service technicians at the supervisory level of the certified applicator. This suggestion is (1) unnecessary in light of the safety record of the pest control industry and (2) incompatible and uneconomical within the structure of our industry.

First, service technician and certified applicator represent two separate and distinct positions. To show the difference in required knowledge and skill at these two levels, our company position descriptions for the two positions are attached. We believe all or most other pest control companies would show an equivalent difference in duties and responsibilities.

To require each position to be tested equally would result in one of only two probabilities. Either the standards for the certified applicator would be reduced--and this is counterproductive--or these standards would remain above the normal ability of the technician. This, too, would be counterproductive.

Such a major change would strike at the foundation of our structural pest control industry. We are a relatively small industry in size, applying approximately 5% of the pesticides used in this country. Our industry is built, as are most all service industries, upon a competent and trained individual working on his own. This technician needs certain knowledge and physical skills. If this technician becomes certified, this person will gain a title to his work position through the state certification process. To replace such an individual for cause, we would have to have available a replacement with certification credentials or we would be unable to deliver the service to our customer pursuant to our contract agreements. Thus, our ability to supervise effectively is lessened by the necessity of meeting an external requirement.

We would note that the regulations issued under Section 4 of FIFRA [40 C.F.R. 171.6(a)] offer broad possibilities for training. We definitely support initial and continuous training of technicians as a superior alternative to testing. We have discussed the desirability of mandatory training with EPA. We believe this to be the preferred direction towards improved technician performance. A program of mandatory and verifiable technician training will blend in well with the efficient state certification programs that are now in place.

As this Committee is aware, our industry is becoming increasingly concerned about the difficulties which would be created by permitting local governments to establish multiple and varying levels of regulation of pesticide use. In 1978, after considerable work by this Committee, the Congress developed an effective clarification of the relative enforcement powers of the States and the Federal Government under FIFRA. This system was designated as State primacy and is now Sections 26 and 27 of FIFRA. This effective system is threatened by many new entrants into the regulation business. We would hope that this Committee would address this issue and clearly establish that the State be the lowest level of regulatory authority. This was clearly stated in original legislative history and has been upheld in several court decisions throughout the country. In this issue, we support our own National Pest Control Association and the other responsible members of the FIFRA Coalition.

In conclusion, I would repeat that training, not universal certification, offers the best avenue for continued improvement. We are equipped to supervise training through our industry, our trade associations, our suppliers and distributors, and our state officials. Let us move accordingly within the safety and efficiency of our free enterprise system.

I thank you for this opportunity to present this testimony and I would be happy to answer any questions which you might have.

BRANCH MANAGER

POSITION DESCRIPTION

BASIC FUNCTION:

This position is responsible for the integrity, ongoing profitability, safety and moral of branch operations through the selection, training, and supervision of branch personnel.

PRINCIPAL ACCOUNTABILITIES:

A. Produce revenue and profit.
B. Understand, administer and enforce all Company policy.
C. Improve the Company's image.
D. Upgrade quality of personnel.
E. Develop all Company employees through training.
F. Insure that employees are fairly compensated and prepared for promotional opportunities.
G. See that quality service is delivered.
H. Collect all funds due the Company.
I. Responsible for the security of all Company property.
J. Maintain buildings, grounds, vehicles, and equipment.

TERMITE TECHNICIAN

POSITION DESCRIPTION

BASIC FUNCTION:

This position is responsible for destroying and preventing the return of termites in home and businesses.

PRINCIPAL ACCOUNTABILITIES:

A. Provide superior termite control service according to established procedures and specifications.
B. Establish and maintain good customer relations.
C. Maintain all equipment in good operating condition.
D. Respond to and resolve customer complaints as they occur.
E. Maintain a neat and professional appearance and manner at all times.
F. Operate a motor vehicle in a safe and efficient manner.
G. Complete and turn in required documentation and paperwork.

STATEMENT OF ROBERT C. KEENEY, VICE PRESIDENT, GOVERNMENT RELATIONS UNITED FRESH FRUIT AND VEGETABLE ASSOCIATION

Mr. Chairman and members of the committee, my name is Robert C. Keeney and I am Vice President of Government Relations for the United Fresh Fruit and Vegetable Association. With me today is Claudia R. Fuquay, Director of Congressional Relations. United is the national trade association for the fresh produce industry. United's members handle over 80 percent of the fresh produce commercially marketed in the United States. We commend the Chairman for taking such an active role in starting these discussions on FIFRA. United's members as agricultural users recognize that the time has come for changes to this law. We look forward to working with you on these issues as Congress fashions legislation that will meet the needs of chemical manufacturers and users, and at the same time, protect consumers and the environment.

Although United generally supports S. 2215, we feel that a number of issues are better addressed in S. 2346 that was recently introduced by Senator Helms. These provisions center on the minor use issues which are extremely important to my members since chemical manufacturers and the EPA generally regard fruits and vegetables as minor crops.

It has been our members' experience that for many minor crops, there is insufficient incentive for chemical manufacturers to invest the appropriate economic resources to develop the data required to register the chemical solely for minor use. The fresh produce industry's arsenal of chemicals in rapidly decreasing.

Title III of S. 2215 addresses reregistration. Of concern to our industry are the proposed reregistration fees. As mentioned earlier, manufacturers are already hesitant at spending the money for the data necessary to reregister many older chemicals that have proven effective for this industry.

As we all know, the data requirements were not as stringent and costly prior to 1978. Because companies are now faced with the new more stringent data requirements, we doubt whether there will be any further registrations or reregistrations of a pesticide only for use on a minor crop.

Of course our industry is not recommending that we remove or lessen safety and health considerations for pesticide use on minor crops. But we do feel that any amendments to FIFRA should recognize the unique needs of producers of these crops as does Title II, Section 211 of S. 2346 by allowing EPA some flexibility in the process including recognition of the special problems for minor crops.

Another area of concern with S. 2215 is in Title X--Export of Pesticides, Sec. 1007--Tolerances for agricultural commodities. This section would require that within 60 days, the Administrator revoke or amend the tolerance of domestic or imported commodities if the registration of a pesticide "has been cancelled, suspended, denied, or voluntarily withdrawn (unless any such action was due solely to environmental effects)."

Our primary concern with this section is that the only exemption is if the pesticide was cancelled "due solely to environmental effects." There are situations where pesticide registrations have been voluntarily withdrawn in the United States for other than health or environmental reasons, such as lack of need by the agricultural community or lack of economic incentive for the manufacturer.

If the United States starts revoking tolerances when there is no health problem, other countries might begin refusing to import U.S. agricultural commodities for the same reason. The produce industry is having a difficult enough time exporting without further retaliation by our trading partners. Many countries must use chemicals that are not needed in the United States because the U.S. either does not grow that particular commodity or does not have the pest problem found in the importing country.

Second, we are quite concerned about the amendments in paragraphs (A) and (B). As written, this language amends the current Food, Drug and Cosmetic Act so that the Department of Health and Human Services (HHS), Food and Drug Administration (FDA) no longer has authority over section 408, "Tolerances for pesticide chemicals in or raw agricultural commodities", or section 409, "Food Additives." If enacted, S. 2215 make this authority solely that of EPA. The reorganization plan establishing EPA, transferred to EPA the functions vested in HHS for establishing tolerances for pesticide chemicals. However, FDA retained enforcement authority and the major authority over food additives. A 1980 "Memorandum of Understanding" between EPA and FDA sets forth the policy of the two agencies regarding their mutual responsibilities. United is concerned as to the administrative delays and possible confusion that these six very short lines in S. 2215 could cause within the agencies.

Title XII, "Employee Protection," also is of concern to this industry. Current U.S. labor laws protect employees from employer retaliation when the worker has, with just cause, filed just complaints against growers. We feel that the language in S. 2215 gives no protection to the employer for acts of harassment by workers and organizations representing workers. Since employees already have such protection under an existing labor law, we suggest the section be deleted from any FIFRA amendments.

United would like to voice its support for three additional amendments that are contained in S. 2346. Currently FIFRA prohibits the EPA Administrator from denying a registration simply because there is another pesticide already registered for use on the same crop against the same pest. We support the amendment of sec. 24 (a) of FIFRA as contained in S. 2346, Title XVII, Sec. 1701 (a)(1) applying this same prohibition to the states. It is critical that the produce industry has available an assortment of pesticides to combat a wide range and ever increasing number of insects.

Section 24 of FIFRA, Authority of the States, prohibits the states from imposing state pesticide labeling or packaging requirements different form those required under FIFRA. We support the amendments to this section contained in S. 2346 Title XVII, Sec. 1701 (a)(2) that would prohibit a state from setting residue tolerances different from those set by EPA. Any residue tolerances set by the state that are different from those set by EPA creates chaos in interstate transport of agricultural commodities and becomes a barrier to trade.

We also support Title X, Sec. 1003 of S. 2346, Liability for Pesticide Use Damage. Our members are farmers, not scientists. They need chemicals in order to feed the world. Not being scientists, they are dependent on accurate label information. We believe that if the user follows the label, then under no circumstances should he be found negligent or liable.

On the other hand, if growers knowingly misuse a product then they should be punished. For this reason we support the penalty section included in S. 2346 which doubles the penalties under current law.

Mr. Chairman and members of the committee, I thank you for this opportunity to present our testimony. United looks forward to working with you and your staff as you proceed on this most important issue.

STATEMENT OF LAWRENCE T. GRAHAM, EXECUTIVE VICE PRESIDENT, NATIONAL FOOD PROCESSORS ASSOCIATION

Mr. Chairman and members of the Committee, I appreciate this opportunity to present testimony today on possible amendments to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). The National Food Processors Association (NFPA) represents about 600 member companies that pack processed-prepared fruits, vegetables, meats, fish and specialty products including canned, frozen, dehydrated, pickled and other preserved food items. Also included among the association's members are companies that provide equipment, supplies and services to the food processing industry.

It is very important to our members that they have an abundant selection of high quality raw agricultural products for the manufacture of a wide variety of processed foods. For this reason, FIFRA is a very important agricultural statute, not just to the farmer who depends on a certain yield per acre, but also to the food processor who seeks safe and economical raw ingredients for his food products.

The bills before us, S. 2215 and S. 2346, represent months of hard work and cooperation between diverse groups with varied interests. NFPA commends these efforts to resolve the concerns of all parties. However, for reasons that I will discuss, we oppose certain provisions of S. 2215 and prefer the alternative approaches in S. 2346. In addition, we support several specific provisions of S. 2346, which covers issues of importance to our members that are not addressed in S. 2215.

Initially, we are concerned that S. 2215 fails adequately to take into account minor use pesticide needs. Many of our members rely upon minor use pesticides for production of a variety of fruit and vegetable products. The general effect of the conditional registration and reregistration provisions of S. 2215 would be to make the registration of new pesticide uses, and the maintenance of old uses, more difficult and expensive. S. 2215 would restrict Environmental Protection Agency (EPA) authority conditionally to register new pesticide uses, would impose short and rigid time frames for reregistration of old pesticides and would substantially increase the costs of reregistration, through reregistration fees and additional data expenses.

We believe that the conditional registration authority in S. 2215 is unduly restrictive, that the reregistration timetable is unrealistically short and too inflexible, and that the imposition of reregistration fees is unwarranted. Since EPA is charged with the responsibility of registering pesticides for public use and benefit, the reregistration process should be paid for through public funds. In recognition of this fact, user fees have been repeatedly voted down in Congress. The cost of government services which benefit society as a whole should not be borne by registrants through reregistration fees. Moreover, these provisions would have a disproportionate adverse impact on minor uses. For these reasons, we support the alternative provisions in S. 2346, introduced last week by Senator Helms. In our view, S. 2346 offers a more realistic reregistration timetable. It also would eliminate reregistration fees and would expressly provide EPA necessary discretion to alter data requirements, where appropriate, to encourage development of minor uses.

We also oppose one aspect of section 1007 of S. 2215, governing tolerances for pesticides. That provision would require

EPA to revoke or amend a pesticide tolerance or exemption in any case where the underlying pesticide registration is cancelled, suspended or voluntarily withdrawn. We do not believe that EPA should be required to revoke or amend the tolerance for a pesticide where the underlying registration has been voluntarily withdrawn in the United States, but where food is imported from countries that continue to permit use of the pesticide, unless EPA can establish that the tolerance is unsafe.

In addition to our concern regarding these provisions of S. 2215, we strongly support several specific provisions of S. 2346, which cover issues of importance to our members that are not addressed in S. 2215.

First, we strongly support the provision of S. 2346 that would establish uniform national pesticide tolerances and prohibit state and local pesticide tolerances different from those established by EPA. Virtually all of our members grow, process and market their food products on a multi-state or national basis. Multiple inconsistent state and local pesticide tolerances frustrate EPA's attempts to set uniform national residue tolerances and disrupt interstate commerce. The need for a strong preemption provision of this kind has been confirmed by recent actions by the State of Massachusetts and other local jurisdictions setting, or proposing to set, residue limits for EDB and daminozide different from those set by EPA.

Only the federal government has the necessary resources, expertise and broad perspective to gather and evaluate the relevant safety, residue and economic data to determine appropriate national pesticide residue tolerances. There should be only one standard for pesticide residues in food shipped in interstate commerce. That standard should be established by EPA and not by fifty different states or thousands of local jurisdictions. The establishment of uniform national tolerances would not in any way detract from the ability of state and local jurisdictions to vigorously enforce consistent tolerances.

Second, we support limitations on the right of states and local jurisdictions to force reliance on a single, or artificially limited number of pesticides. Section 3 of FIFRA prohibits the Administrator of EPA from denying registration of any pesticide simply because another pesticide is available, referred to as a "lack of essentiality." We feel very strongly that FIFRA section 24 should be amended, as provided for in S. 2346, also to prohibit states from using "lack of essentiality" as the sole criterion in denying registration of a pesticide. Alternative pesticides are essential for maximum flexibility in pest management programs, especially with the increasing resistance capabilities of pests. A prohibition against use of "lack of essentiality" would assure that states register pesticides based on their own merits, but would not impair state authority to deny approval on other grounds.

Third, the food processing industry must have the assurance that agricultural chemicals were used properly in the production of crops and ingredients. With this in mind, we support provisions in S. 2346 calling for expanded and updated training and retraining programs for both certified and non-certified pesticide applicators. Non-certified applicators, mixers and loaders would be required to validate this training to the state, as is currently required of certified applicators. Farmers who can demonstrate that they have followed all label instructions and prohibitions would be held unliable for unforeseen environmental or other effects of pesticide use.

Mr. Chairman, that concludes my testimony. I would be happy to answer any questions you may have and to work with the Committee on this important issue.

STATEMENT OF
BENJAMIN C. BOLUSKY

It is with great pleasure that the American Association of Nurserymen welcomes this opportunity to comment on the proposed amendments (S.2215 and S.2346) to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

The American Association of Nurserymen (AAN) is the national trade organization of the nursery, landscape and garden center industries. AAN represents more than 3,500 firms engaged in all aspects of the nursery industry, including the grower, wholesale and retail segments. We estimate that approximately 5,350 commercial growers produced nursery crops valued at $2.0 billion in 1985. These growers employ approximately 60,000 persons year-round, doubling to 120,000 during the peak seasons.

Our members are overwhelmingly small businesses who depend upon the availability of safe pesticides. As pesticide users, the nursery industry views environmental safety and the safe use of pesticides to be of paramount importance. We wholeheartedly support FIFRA's invaluable role in ensuring only safe pesticides reach the marketplace and in delineating the safe use of such pesticides. The Environmental Protection Agency (EPA) should be commended for its effective and proper enforcement of the existing FIFRA.

HOW PESTICIDES REACH THE NURSERY INDUSTRY

Pesticides reach the nursery marketplace in a number of ways. Some will be developed primarily for the living plant industry and will be registered and labeled accordingly. However, most pesticides traverse through the registration process tested for certain pests and/or crops not related to the nursery industry. In light thereof, and in cooperation with other agricultural groups in 1978, AAN successfully urged Congress to amend Section 2 (ee) to permit the application of a pesticide against any target pest not specified on the label if the application to crop, animal or site is specified on the label.

Section 24(c) of FIFRA represents another method by which permission is obtained to use pesticides on nursery crops. Section 24(c) is a state registration for "special local needs." If a pesticide has been registered federally for some other use, a state pesticide authority may grant a registration for a specific nursery use, although it should be noted that a 24(c) registration is authorization for use only in that state.

Perhaps the most important means by which pesticides reach the nursery industry is the result of the Inter-Regional Project #4 which was established in 1963 by the Department of Agriculture and state agricultural experiment stations. IR-4 conducts the research necessary to make pesticides registered for other uses available to the nursery industry. Without question, IR-4 is one of the most important government research programs to the nursery industry. Regrettably, the Administration's FY87 budget proposes to "zero-out" the IR-4 program. While AAN is vigorously opposing the elimination of IR-4, its future is uncertain at this given time. Needless to say, the nursery industry will be extraordinarily hard-pressed without IR-4. So, while debating legislation to amend FIFRA, we respectfully implore Congress to bear in mind the consequences of greatly diminished availability of pesticides to the nursery industry should the Administration succeed in dismantling IR-4.

THE NURSERY INDUSTRY IS A MINOR USE MARKET

Registration entails significant testing and data preparation costs for both the pesticide manufacturer and the government. For many comparatively small-scale or specialty pesticide uses such as the nursery industry, there is insufficient economic incentive to entice pesticide manufacturers to develop the data needed to register such uses in accordance with FIFRA and the Federal Food, Drug and Cosmetic Act. Potential liability costs are often an additional disincentive. As a result, it is not surprising that pesticide manufacturers concentrate on those registrations which will have the greatest impact upon the agricultural/horticultural community.

Nursery production has never been considered a sufficiently large potential pesticide market to warrant all of the necessary research, development and registration costs of new pesticides. It has always been more economically feasible for manufacturers to develop pesticides for "major" markets such as corn, wheat and soybeans, if for no other reason than an acre of corn for example, contains only corn. By comparison, a nursery acre can contain up to 25 different varieties of growing plants requiring many different pesticides within that single acre. It is clear to see then that the nursery industry is forced to rely upon pesticides developed for the "major" markets, because as such new pesticides are manufactured, the older pesticide products become the available domain of the smaller and "minor use" markets of which the nursery industry has long been identified.

By the same token, and virtue of its status as a minor use, the nursery industry is disproportionately susceptible to the loss of pesticides from the marketplace. For example, EPA halted the use of chlordane in 1979 which was used to treat Japanese beetles and grubs on nursery stock destined for export to Canada. No acceptable replacement for chlordane has yet been obtained so nursery shipments to Canada have been significantly curtailed for the last seven years. Although a real need has existed, no pesticide manufacturer has produced a chlordane replacement partly because the nursery industry is regarded as a minor use industry and does not represent a sufficiently large pesticide market.

It is imperative, therefore, that Congress fully appreciate the susceptibility of minor use industries (such as nurseries) to the loss or removal of approved minor use pesticides by either chemical manufacturers or EPA. Congress must also recognize that development of new pesticides and access to already registered pesticides for ultimate use by the nursery and other minor use industries will depend to a great extent upon the difficulty registrants have in introducing new pesticides or in adding new uses to existing labels. Regulations speaking to the safety of pesticides and their safe use -- not exorbitant re/registration fees--should control which pesticides will and will not be marketed for minor uses. Therefore, AAN urges Congress to grant an exemption for reregistration fees for pesticides used on agricultural nonfood or feed minor use crops - especially pesticides under the IR-4 program. AAN also urges Congress to reaffirm the 1978 FIFRA amendments which have benefitted minor uses by directing EPA to make minor use data requirements commensurate with the anticipated extent and pattern of use.

NEED FOR REAFFIRMATION OF THE EXISTING FEDERAL PREEMPTION OVER LOCAL PESTICIDE USE REGULATIONS

In 1972, Congress amended Section 24(a) of FIFRA by passing the Federal Environmental Pesticide Control Act which granted pesticide regulatory authority to the states -- not to local jurisdiction. The intent of Congress was perfectly clear:

> The Senate Agriculture Committee considered the decision of the House Committee to deprive political subdivisions of states and other local authorities of any authority of jurisdiction over pesticides and concurs with the decision of the House of Representatives. Clearly, the fifty states and the Federal Government provide sufficient jurisdictions to properly regulate pesticides. Moreover, few, if any, local authorities whether towns, counties, villages, or municipalities have the financial wherewithal to provide necessary expert regulation comparable with that provided by the State and Federal Governments. On this basis and on the basis that permitting such regulation would be an extreme burden on interstate commerce, *it is the intent that Section 24,* by not providing any authority to political subdivisions and local authorities of or in the States, should be understood as depriving such local authorities and political subdivisions of any and all jurisdiction and authority over pesticides and the regulation of pesticides. *3 U. S. Code Cong. & Ad. News, p. 4008 (1972) (Emphasis added).*

Despite this explicit directive of Congressional intent preempting local jurisdictions from regulating the use of pesticides, such local jurisdictions are enacting restrictions and regulating the use of pesticides *even* when such pesticides have already undergone all of the necessary extensive registration tests and have been certified for safe use by state and federal governments.

Local regulation of pesticide uses is simply and unnecessarily disruptive, particularly in light of the extensive registration systems at the state and federal governments. A multiplicity of local ordinances differing from one jurisdiction to another inevitably creates a fragmented checkerboard of forced compliance to which few users -- particularly minor users such as nurserymen--could adhere even if they could afford to do so. The result of this growing lack of uniformity will soon cause exorbitant costs associated with increased inventory maintenance - not to mention the costs involved with compliance recordkeeping.

Aside from the fact that pesticides are certified for use only after extensive testing, local jurisdictions generally lack the scientific expertise to enact appropriate restrictions. As a result, local ordinances devoid of and not based upon proper scientific evidence are "popping up" around the country. Montgomery and Prince George's Counties in Maryland are but two local examples of a growing national problem. Such ordinances are unnecessarily complicating an admittedly complex system which is already properly based on scientific determinations related to the risks and benefits of pesticides.

AAN thus respectfully urges Congress to reaffirm its original intent and to preempt explicitly and statutorily local jurisdictions from regulating the use of pesticides when such pesticides and their uses have already been approved by the state and federal governments.

However, AAN recognizes the political sensitivity involved with such an amendment. Therefore, we would support an alternative approach which would respect the role of localities to protect their residents, while simultaneously bring a sorely needed halt to local distortions of federal and state pesticide regulations. AAN would support language requiring the states to receive petitions from local jurisdictions requesting regulations over pesticides. The states would investigate such petitions, and where appropriate, exercise their enforcement or regulatory authority on behalf of the local jurisdiction. With respect to existing local pesticide regulations, we envision a limited grace period whereby local jurisdictions would petition the states to incorporate such local ordiances into the states' regulatory codes. AAN believes this proposal retains the intended integrity of the current regulatory process, while providing a mechanism by which local jurisdictions can have their concerns investigated and addressed by responsible state regulation.

TRAINING, CERTIFICATION AND RIGHT-TO-KNOW

At the present time, negotiations with EPA are continuing in an effort to develop Farmworker Protection Standards for agricultural workers who handle or may be exposed to pesticides. AAN has been a very active participant in these negotiations and expects the issuance of such regulations shortly. Inasmuch as these regulations incorporate a broad realm of provisions including training requirements, it is important that Congress be mindful of these negotiations if and when it considers training, certification and right-to-know issues related to FIFRA legislation. It is imperative that any such possible FIFRA amendments be compatible with the Farmworker Protection Standards, otherwise confusion and chaos will reign throughout the agricultural community.

S.2215 and S.2346

S.2215 represents the culmination of a cooperative effort by the National Agricultural Chemicals Association (NACA) and the Campaign for Pesticide Reform (CPR) which is an environmentalist coalition. These groups are to be commended for their joint efforts in reviewing the existing FIFRA and in proposing S.2215 containing several proposals of merit. Regrettably, though, user industries and groups such as AAN were not asked to participate. As a result, we believe S.2215 does not adequately reflect the many concerns experienced and shared by many minor use industries including nurserymen as outlined above. In addition, we respectfully urge Congress to examine closely the effects of S.2215 upon EPA's time and resources. It seems to us that many provisions of S.2215, the re/registration timetables for example, are neither realistic nor cost effective.

AAN supports amendments to FIFRA provided such incorporate appropriate and necessary treatment of minor use pesticides. Therefore, we support S.2346 introduced recently by the distinguished Chairman of this Committee - Senator Jesse Helms. AAN believes that S.2346 more closely reflects and understands the important concerns of minor use pesticides, as well as their impacts upon the nursery and other minor use industries.

CONCLUSION

Mr. Chairman, the American Association of Nurserymen is committed to seeing FIFRA amendments passed this year. We are prepared and willing to cooperate fully to ensure such comes to fruition. Yet, we wish to remind this committee that the nursery industry is dependent upon the availability of affordable and safe minor use pesticides. Therefore, when enacting final legislation it is encumbent upon Congress to consider carefully all of the broad impacts any FIFRA amendments will have upon the viability of small businesses (such as nurserymen) who compose the majority of the minor use markets in this country.

Thank you, Mr. Chairman, for this opportunity to present the views of the nursery industry regarding amendments to FIFRA.

STATEMENT OF
PETER BARTON HUTT
ON BEHALF OF
GROCERY MANUFACTURERS OF AMERICA, INC.
BEFORE THE
SENATE COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY
ON
NATIONAL UNIFORMITY IN THE REGULATION OF
PESTICIDE RESIDUES IN OR ON FOOD
APRIL 30, 1986

Mr. Chairman and members of the Committee, I am Peter Barton Hutt, a partner in the law firm of Covington & Burling. During 1971-1975, I served as Chief Counsel for the Food and Drug Administration (FDA). I am appearing today on behalf of the Grocery Manufacturers of America, Inc. (GMA).

GMA is a 75-year-old national trade association, comprised of over 130 companies which manufacture food and other products sold in retail grocery stores throughout the United States. GMA member companies employ over 2.5 million people nationwide and have annual sales in excess of $250 billion.

My testimony today addresses the critical need for legislation to assure national uniformity in the regulation of the levels of pesticide residues in or on food. GMA believes that this is a matter of great importance to agricultural producers, food processors, and the public at large.

Background

National uniformity legislation is needed because virtually every State has one or more laws regulating the levels of pesticide residues in or on food, and repeated attempts to achieve national uniformity in the enforcement of these laws have been unsuccessful. Pesticides are of critical importance to food production in this country, and our nationwide food production and marketing system depends upon uniformity in their regulation.

The growth of State and Local laws. In the early days of this country, food was consumed where it was grown. As urban cities began to develop in the 1800s, local food markets were established to fill the need. Town ordinances were adopted to regulate the food supply in those days. As our cities grew larger, and food distribution expanded, County laws were established to regulate the food supply as well. By the mid-1800s, States were also enacting regulatory laws in this area. Because food production and distribution was still primarily a local or regional matter throughout the 1800s, however, there was no Federal law establishing a nationwide food safety policy until after 1900.

The enactment of Federal laws. Shortly after 1900, Congress enacted two laws to regulate pesticides in food: the Food and Drugs Act of 1906, and the Insecticides Act of 1910. Because of the narrow interpretation of the Commerce Clause by the Supreme Court at that time, however, both statutes were very limited in their jurisdiction. Food produced and distributed locally was not covered. Supreme Court decisions during the early 1900s therefore ruled that these Federal laws did not preclude different requirements in State and Local laws.

Both of these early Federal laws were subsequently replaced by more modern laws that regulate virtually every aspect of the safety of pesticides in food: the Federal Food, Drug, and Cosmetic Act of 1938 and the Federal Insecticide, Fungicide, and Rodenticide Act of 1947, both of which have since been amended numerous times. By the time these laws were enacted, however, it was too late for them to serve as a model for State and Local legislation or to make enactment of State and Local legislation unnecessary in this area. The tradition of State and Local laws regulating the levels of pesticides in food was already well-established and has continued to this day.

The repeated failure of non-legislative attempts to achieve national uniformity. Following enactment of the Food and Drugs Act of 1906, FDA's predecessor agency, the USDA Bureau of Chemistry, made major efforts to achieve national uniformity in this area. The 1914 Annual Report of the Bureau of Chemistry reported cooperative efforts with State officials that "should very largely overcome the lack of uniformity." A report on the progress achieved during the first ten years under the 1906 Act, contained in the 1917 Annual Report, related attempts to deal with "much confusion and apparent conflict between the local and Federal laws and the local and Federal administration of the laws," resulting in "extra cost, which naturally was passed on to the ultimate consumer." The 1921 Annual Report similarly reflected the fact that "both officials and manufacturers complained greatly of the lack of uniformity in the exercise of food control by the Federal and State Governments:"

> "Lack of uniformity increases the cost of doing business, and the increased cost is usually passed on to the consumer. It arises not merely from differences in the various laws but also from differences in the interpretation of the laws by the officials and the application by them of different standards to the same product in different jurisdictions."

FDA has repeatedly sought to deal with this problem in the years since then.

State and Local officials have also been concerned about this problem. The Association of Food and Drug Officials (AFDO), whose membership includes regulatory officials from all of the States, was formed in 1897 for the purpose of producing national uniformity in food and drug regulation and has continuously urged that principle ever since. In 1941, for example, the Association's president criticized "trade barriers that forced many producers and manufacturers to live under the virtual dictatorship of localized bureaucracy" and urged State food and drug officials to "discourage the enactment of laws that make it impossible for legitimate industry of one state to engage in trade in another under conditions which are fair and equitable." That year, AFDO adopted a resolution expressing "disapproval of the tendency toward the enactment of legislation which constitutes definite barriers to Commerce between the states." Numerous similar resolutions have been adopted by AFDO since then. Nonetheless, in 1973 the Association passed yet another resolution acknowledging, as well as disapproving, "a growing trend that . . . some States and local agencies are passing laws, regulations, or ordinances which are inconsistent with the principle of uniformity to which A.F.D.O.U.S. is committed." More recently, AFDO has established still another committee to study the matter.

Numerous other national reports have reflected on, and disapproved, nonuniform laws and regulations in this area. In 1939, a USDA report on "Barriers to Internal Trade in Farm Products" found varying or inconsistent State requirements created increasingly serious barriers to national food distribution. A study conducted by the Public Administration Service for FDA in 1963 on State and Local food and drug programs concluded that:

> "The general food and drug laws of the states fail to reveal a basic uniformity among themselves or an adequate correspondence with federal legislation. *** Differences in laws and regulations are excessive, and many serve no useful purpose; the total body of state and local food and drug laws is a confusing and disjointed mass."

The National Commission on Food Marketing, established by Congress in 1964 to appraise the marketing structure of the food industry, stated that "conflicts among the profusion of State regulations . . . are a significant burden on interstate trade in food products" and concluded that:

> "We therefore believe that a concerted effort should be made to effect uniformity among State regulations that obstruct trade in foods across State lines."

The Report of the White House Conference on Food, Nutrition and Health in 1969 similarly found that "under present Federal, State and local law, different and often inconsistent regulatory requirements . . . prevail throughout the Nation" and that these requirements:

> "result in artificial trade barriers that impede the orderly marketing of foods, hinder sound nutrition, raise the cost of new foods to consumers, and directly interfere with the public interest. *** This situation cannot be justified on public health grounds, and reflects the lack of any attempt to establish and maintain a national policy on foods that reflects the interest of consumers."

The Report of the White House Conference therefore recommended "Uniform application of all regulatory requirements throughout the Nation, enforceable by Federal, State, and local officials."

Congress has also recognized the unproductive burden that inconsistent State requirements impose upon farmers, food processors, and consumers. The 1906 House Report on the legislation that ultimately became the Food and Drugs Act of 1906 stated that:

> "the laws and regulations of the different States are diverse, confusing, and often contradictory. What one State now requires the adjoining State may forbid. Our food products are not raised principally in the States of their consumption.
>
> State boundary lines are unknown in our commerce, except by reason of local regulations and laws, such as State pure-food laws. It is desirable, as far as possible, that the commerce between the States be unhindered."

When Congress considered enactment of a new national food and drug law in the 1930s, the 1935 Senate Report on that legislation, which ultimately became the Federal Food, Drug, and Cosmetic Act of 1938, acknowledged the "problem of uniformity" and stated that the "States have unanimously urged the Federal Government to take leadership in modernizing existing law." Neither the 1906 Act nor the 1938 Act expressly required national uniformity, however, and such uniformity has therefore not been achieved.

None of these non-legislative attempts have brought the country closer to national uniformity in the regulation of the safety of pesticide in or on foods. It is apparent that non-legislative approaches have repeatedly failed and will continue to fail in the future.

The importance of pesticides to food production. Pesticides make a major contribution to a plentiful and wholesome food supply by protecting it from insect destruction and insect-carried disease. USDA has estimated that losses due to pests, insects, and disease run as high as 40 percent in some countries. The National Academy of Sciences has stated that, in the United States, insect control annually prevents about $6.5 billion in agriculture losses. Pesticides thus increase farm income, reduce inflation in food costs, and permit American families to spend less of their income on food.

The critical need for uniformity in a nationwide food production and marketing system. Although food production and marketing began as an entirely local matter in the early 1800s, the United States has now become one large nationwide food market. Pesticides are used in food production throughout the country, and that food is in turn distributed in every State throughout the nation. Local and even regional markets have disappeared.

Nonuniform laws, regulations, and other requirements have a direct and immediate impact upon food production. Conflicting prohibitions or requirements for residues of pesticides in food, or different labeling requirements, discourage food processors from using the food, confuse and scare food retailers and consumers, add substantial cost to the distribution and marketing of food, and thus disrupt farm markets and reduce farm income. Uniform national regulation of the levels of residues of pesticides in or on food is essential to a sound national agricultural program.

Inconsistent determinations, or additional regulatory requirements, result in an enormous economic burden upon consumers, for no public health benefits. Taxpayers should support a single uniform pesticide residue level determination, not duplicative determinations in every State throughout the country. Conflicting or additional regulatory requirements in different jurisdictions require the food industry to pay more for compliance, disrupt normal marketing practices, and thus increase food prices to consumers.

Citizens who live in one part of the country are no less entitled to protection than those who live in another. Our citizens also travel widely throughout the country, and are entitled to the same protection in every State they visit. Determinations about the levels of residues of pesticides in or on food must therefore be consistent in every jurisdiction in this country.

State and Local enforcement of uniform requirements for the levels of residues of pesticides in or on food will enhance a safe food supply throughout the country and thus increase consumer protection. Deploying State and Local resources away from duplicative and conflicting pesticide residue level determinations, and into enforcement of uniform national regulatory policies, represents the wisest expenditure of public funds.

In an article published in 1983, the Counsel to the Vice President stated that President Reagan's New Federalism initiative, which is designed to encourage greater responsibility at the State and Local level, includes:

> "recognition that state and local administration of regulatory programs may conflict in some instances with other goals of regulatory relief or with other important federal interests. For example, individual states may operate specific programs more effectively than the federal government, but the combined effect of disparate state regulatory standards may intolerably burden interstate commerce, thus requiring uniform federal regulation."

Recognizing "the need for a strong central government to promote commerce and other federal interests," he distinguished between those matters that are primarily local in nature and those that involve such "burdens on interstate commerce" that national uniformity is required.

In December 1984, the Administrative Conference of the United States issued a report and recommendation that echoed these principles. While recognizing that "state governments are normally in a better position than the federal government to determine the types of regulations that will serve the interest of the states' citizens," the report also found that "States sometimes have an incentive, however, to impose regulations that advance state interests at the expense of other states' interests or of national interests." The report concluded that, because of the limited "checks on state regulation that harms the national interest:"

> "states possess, in practice, the power to make regulatory choices that produce net benefits within the state but that produce substantial net detriments on a national level. Without an additional federal constraint on state regulatory power, states can be expected to regulate in this manner frequently."

The Administrative Conference therefore recommended that Congress and the Federal agencies directly address the problem of national uniformity in regulatory policies in order to protect nationwide interests.

The ethylene dibromide and daminozide examples. Within the past three years, two specific situations have arisen that illustrate the chaos, confusion, and economic waste that can occur when States impose restrictions on the levels of pesticide residues in or on food different from those imposed by EPA and FDA. The first involved ethylene dibromide (EDB), and the second involves daminozide.

Ethylene dibromide (EDB). For many years, EPA had registered EDB for use on certain food crops and had exempted it from the need for a tolerance. When new information became known about its potential toxicity, EPA began a systematic review of the information, leading ultimately to an orderly withdrawal of this pesticide from the market.

In December 1983, in the middle of this orderly EPA process, the State of Florida took unilateral action to ban any food product found to contain any detectable amount of EDB. About two months later, EPA and FDA imposed new limitations on the permissible levels of residues of EDB for agricultural commodities, intermediate food products, and ready-to-eat food, that provided a wide margin of safety for the public. Notwithstanding this action by the responsible Federal agencies, a number of States refused to accept the Federal limitations and instead imposed their own. Today, there remain four different requirements for levels of EDB residues in or on food: the Federal requirements, requirements set by Massachusetts and Maine, requirements set by New York and New Jersey, and requirements set by California.

Some of these requirements, which set a zero residue level, were inherently impossible to meet. Not only could the agricultural community and the food industry not segregate food products to meet these requirements, but in many food categories there simply were no products that could satisfy a zero tolerance for EDB. Nor was there any valid public health rationale for the different and additional restrictions added by the States, or any pretense that the conditions within those States differed in any way from the conditions found throughout the rest of the country.

Even more important, in a nationwide food market it is impossible for farmers and food processors to comply with differing requirements relating to permissible levels of pesticide residues throughout the country. A given raw agricultural commodity may be grown in one State, stored for a period of time in another, partially processed in a third, made into a finished food product in a fourth, sent to a distribution warehouse in a fifth, and from there sold to consumers in retail stores in several nearby States or throughout the country. Unless the pesticide residue requirements are uniform, our modern food distribution system cannot function.

Action by a State to set different levels for pesticide residues also creates confusion in international markets. The Soviet Union, for example, expressed grave concern about accepting grain that met the Federal, but not all of the State, requirements for EDB.

Daminozide. More recently, the same problem has arisen with yet another pesticide, daminozide. The EPA Scientific Advisory Panel concluded in September 1985 that the available scientific data do not demonstrate that daminozide is a carcinogen. Based upon that scientific evaluation by recognized independent experts in the field, EPA reduced the permissible residue level of daminozide and undertook additional steps to obtain sufficient information to determine what additional action is warranted to protect the public health. In spite of this responsible Federal action designed to provide ample public health protection, the State of Massachusetts has recently proposed three alternative actions to establish permissible levels of daminozide within Massachusetts. Two of those alternatives would differ substantially from the Federal action. Not to be outdone, GMA has just been informed that Maine is considering yet another approach, that would differ both from Massachusetts and from EPA.

In this instance, not only EPA and FDA, but also a broad-based national group of independent scientific experts, have concluded that there is no public health justification for restrictions beyond those imposed by EPA. Neither Massachusetts nor Maine contends that the conditions in those States differ in any material way from the conditions that exist throughout the rest of the country. If this kind of State and Local action is permitted to continue, it could only lead to a series of similar actions by any State, County, or City official throughout the country, based entirely upon local political considerations. Farmers, the food industry, and consumers would pay heavily, for no additional public health protection.

Principles that Should be Incorporated in National Uniformity Legislation

National uniformity legislation should be enacted in order to reflect the intent of Congress to assure a safe and reasonably priced food supply for consumers. Such legislation should protect the interests of food producers, food distributors, and food consumers alike.

The purpose of the legislation. The legislation should be designed to assure national uniformity in both the determinations of permissible levels of residues of pesticides in or on food and the resulting regulatory requirements and prohibitions involved in the regulation of the levels of residues of pesticides in or on food. Uniformity should extend from the raw agricultural commodities through to the final processed food, from the farmer to the consumer. Federal laws, regulations, and interpretations should be controlling throughout the country. State and Local officials should be empowered to enforce these Federal determinations, thus assuring more widespread, complete, and thorough application of these uniform determinations. To make certain that any local needs are not overlooked, however, the legislation should also provide for exemptions from the general rule of national uniformity where they are justified.

The coverage of the legislation. The legislation should provide for national uniformity in the regulation of the levels of residues of pesticides in or on food under two federal statutes: the Federal Food, Drug, and Cosmetic Act and the Federal Insecticide, Fungicide, and Rodenticide Act. Under these statutes, EPA registers pesticides, establishes tolerances for residues in or on raw agricultural commodities of a pesticide registered for use with those commodities, and promulgates food additive regulations for residues in processed food made from the raw agricultural commodities for which a pesticide has been registered. FDA establishes concern levels, action levels, and tolerances for pesticide residues for which EPA has not taken appropriate action under its authority, establishes all requirements for food labeling related to the safety of pesticides, and enforces both EPA and FDA pesticide requirements as they relate to food products. Taken together, these Federal statutes authorize EPA and FDA to regulate every aspect of the safety of pesticides in or on food.

The legislation should encompass all regulation of the levels of residues of pesticides in or on food. This should be given a very broad interpretation, to include any inert ingredient, metabolite, breakdown product, or similar substance in or on food that results from the use of a pesticide.

The types of regulatory decisions included. The legislation should apply to both formal and informal regulatory decisions made by EPA and FDA within the scope of the two Federal statutes involved. These include decisions made under the two statutes in the form of regulations and interpretations. EPA and FDA decisions relating to the levels of residues of pesticides in or on food may, for example, be announced through formal regulations or through informal speeches, press releases, letters, and personal discussion. Such decisions may come in the form of specific regulatory requirements or prohibitions, or in the form of explicit conclusions that no enforcement or other regulatory action is justified. Informal decisions are often as important in the regulation of pesticide residue levels in or on food as formal decisions. The legislation should therefore apply equally to whatever type of explicit regulatory decision is involved.

The EPA and FDA regulatory decisions that should be included under the legislation may be in the form of a requirement or prohibition or a decision not to take regulatory action. For example, EPA and FDA may impose limits on residues, a requirement for information to appear on product labels, or posters in stores or restaurants, or may specifically decide any or all of these are not warranted. EPA may exempt a pesticide from the requirement of a specific tolerance in food, thus permitting any level lawfully to occur in that food. FDA may conclude that de minimis residues are safe and should not be the subject of enforcement action. All of these types of explicit Federal regulatory decisions establish a permissible level for a pesticide in or on food and thus should be included within the legislation.

The legislation need not, however, cover regulatory decisions relating to the safety of pesticides other than in or on food. Thus, the legislation need not relate to the registration or application of pesticides. It need not in any way cover the safety of workers who manufacture pesticides or the safety of workers who are applying pesticides to foods or who are in the vicinity when pesticides are applied to food.

Nor should the legislation cover regulatory inaction that is not based upon an explicit decision made by EPA or FDA. Only a specific Federal determination relating to a permissible level for a residue of a pesticide in or on a food should be covered by the legislation. An FDA decision not to bring enforcement action against illegal pesticide levels because of a lack of resources or other priorities should not preclude State enforcement action. The failure of the Federal agencies to make a determination about the safety of a pesticide residue should also leave the States free to take their own action, until EPA or FDA makes a specific regulatory decision on the matter. Thus, the legislation should make certain that only documented explicit Federal determinations trigger the requirement of national uniformity.

Once an explicit Federal determination is made relating to a permissible level of a residue of a pesticide in or on food, however, a State or Local government should not be permitted to establish a different requirement or prohibition, either directly or indirectly. Thus, a State should not be allowed to ban food meeting the Federal level, or take any other form of enforcement action based on that level, such as imposing civil fines or criminal penalties. Nor should the State be allowed to use other indirect means to impose its own regulatory burdens relating to a pesticide residue level permitted under Federal law, such as a labeling requirement or posters in stores and restaurants, where EPA and FDA have not imposed such requirements. Once permissible Federal levels are explicitly set, they should establish a uniform national system of regulation unless and until a State obtains an exemption from EPA or FDA authorizing it to impose its own local requirements or prohibitions, or the State determines that an imminent hazard exists.

Federal-State cooperation. The legislation should explicitly provide that State and Local officials may exercise concurrent jurisdiction with EPA and FDA to enforce requirements or prohibitions identical with those established under Federal law. Such State and Local enforcement would greatly strengthen consumer protection. To facilitate uniform national regulation, the legislation should require EPA and FDA to cooperate with State and Local officials by providing relevant information and training programs, and by entering into contracts for enforcement activities as authorized by appropriations statutes. Such requirements would reflect a long-standing joint commitment of Federal and State officials to uniform national enforcement of regulatory requirements and prohibitions relating to the levels of residues of pesticides in or on food.

Adoption of State requirements as Federal requirements. The legislation should reflect the fact that State and Local governments, with long experience in the regulation of pesticides in food, may well have useful suggestions for improving EPA and FDA implementation of the Federal statutes regulating the levels of pesticides in or on food. Any State or Local government should be authorized to petition EPA or FDA to adopt by regulation, as a Federal requirement or prohibition, an existing or proposed State or Local requirement or prohibition. Within 180 days after receipt of any such petition, EPA or FDA should be required to respond specifying the substantive action that is being taken on it, either granting or denying the petition in whole or in part. If that substantive action is a denial of the petition, that should end the matter except for any court appeal. If that substantive action grants the petition, in whole or in part, EPA or FDA should also be required to initiate, within that statutory 180-day period, whatever administrative proceedings are required to implement it. This would ordinarily be a notice of proposed rulemaking.

Thus, the legislation should require a substantive decision by EPA or FDA, and any implementing action, within 180 days. The Federal agencies should be granted no discretion in complying with this time limit. It should be made clear that any failure to comply with the 180-day requirement would be handled by a mandamus order from a Federal court, requiring immediate compliance.

If the Federal agencies nonetheless did not provide a substantive decision and any implementing action within the required 180 days, the legislation should allow the State or Local jurisdiction to establish in its own jurisdiction the requirement or prohibition that is the subject of its petition, on an interim basis. This interim requirement or prohibition could be contested by any person through a declaratory judgment action in the courts. If such a challenge were brought, the State or Local jurisdiction would bear the burden of proving that the interim requirement or prohibition meets the statutory standards. The interim requirement or prohibition would remain in effect until the Federal agency rules on the underlying petition and initiates any appropriate administrative action, or a court determines that the interim requirement or prohibition does not meet the statutory standards, whichever occurs earlier.

These statutory provisions would assure State and Local officials that their voices would be heard, and would require EPA and FDA to review and take prompt action upon any State or Local suggestion. In this way, the experience of State and Local officials would be directly reflected in Federal decisions.

Exemptions for State and Local governments. Although, as a general rule, requirements and prohibitions involving the levels of residues of pesticides in or on food should be uniform throughout the country, there may be some situations where exceptions are justified on a local basis. The legislation should therefore specifically allow State or Local governments to petition EPA and FDA for an exemption from the general rule of national uniformity. The Federal agency involved should be authorized to promulgate a regulation granting such an exemption, after notice and opportunity for an oral hearing, under whatever conditions are appropriate to protect Federal interests.

To justify such an exemption, the State or Local government should be required to demonstrate either that there are compelling and unique local conditions that do not exist elsewhere in the United States, or that the subject matter involved is primarily local in nature and the Federal agencies are not exercising jurisdiction over it. In both cases, the exemption should be further justified by a showing that the State or Local requirement or prohibition protects an important public interest, would not cause any food to be in violation of Federal law, and would not unduly burden interstate commerce. Under these circumstances, a State or Local government should be permitted, through the exemption, to impose its own nonuniform requirement or prohibition that is in addition to or different from the Federal requirements and prohibitions, but no other jurisdiction should be able to do so without obtaining its own exemption.

The State and Local advisory committee. Because a truly effective uniform national implementation of all laws regulating the levels of residues of pesticides in or on food depends upon strong State and Local cooperation, the legislation should provide for the establishment by EPA and FDA of an advisory committee comprised of State and Local officials engaged in this area of regulation. This advisory committee should be is charged with assuring that State and Local interests are fully protected and considered in EPA and FDA decisions relating to the levels of residues of pesticides in or on food. It should be responsible for coordinating the views of all State and Local officials working in this area, for presentation to EPA and FDA, and in turn disseminating important information from EPA and FDA to State and Local governments. In this way, communication and coordination would be substantially improved and more effective enforcement of the law would be fostered throughout the country.

The highest Federal official should decide the matter. State and Local officials uniformly fear that Federal agencies pay little or no attention to their petitions. To add further assurance that this would not happen, the legislation should provide that any petition by a State or Local government, requesting that the Federal agency adopt a State or Local requirement or prohibition or that the State or Local jurisdiction be granted an exemption, must be decided by the highest Federal official responsible for the implementation of the Federal law involved (e.g., the Commissioner of FDA or the Administrator of EPA). This authority should not be permitted to be delegated. Before that highest Federal official decides the matter, moreover, the advice of the advisory committee comprised of State and Local officials should also be required to be obtained, except where an imminent hazard is involved. These provisions would assure that State and Local petitions would receive adequate review and attention at the highest level of the Federal government.

Exemptions to prevent an imminent hazard. The legislation should also recognize the need for a State or Local government to establish, within its own jurisdiction, a requirement or prohibition that is necessary to prevent an imminent hazard. After the State or Local official has provided an opportunity both for written comment and for a public hearing, the State or Local jurisdiction should be authorized to adopt its own permissible level for a pesticide residue in or on food that is different from the Federal level if it has been demonstrated that there is an imminent hazard to public health and that the additional protection provided by the State or Local level is necessary to prevent that imminent hazard. An imminent hazard should be defined as a hazard that presents an unreasonable, direct, and substantial danger to the health of individuals. Within ten days after announcing that a requirement or prohibition is being promulgated under this provision, the State or Local official should be required to submit a petition requesting the responsible Federal agency to adopt the State or Local requirement as a Federal requirement or to permit a State or Local exemption. If no such petition is submitted, the State or Local action should automatically become void.

Like the interim level that could be established when a Federal agency fails to respond to a petition within the 180-day statutory period, the imminent hazard level should remain in effect only until such time as the Federal agency takes appropriate action on the petition submitted by the State or Local official or a court rules that the State or Local level does not meet the statutory standards. Any person should be able to challenge the State or Local level through a declaratory judgment action in the courts, and the

State or Local jurisdiction should bear the burden of demonstrating compliance with the statutory standards.

Such a provision would recognize the need of State and Local officials to have adequate authority to protect the public health within their jurisdictions, without imposing an undue burden on interstate commerce. Where an imminent hazard was in fact shown to exist, based upon an adequate public record, State and Local officials would remain free to take action to prevent that hazard. Where no such hazard existed, however, the general rule of national uniformity would continue to prevail.

Conclusion

Only the Federal government has the funding, scientific personnel, and facilities needed to obtain and evaluate the complex factual and scientific information underlying the public policy issues raised by the use of pesticides in producing food, and the resulting levels of residues of those pesticides in or on food products. EPA and FDA not only have extensive capability in their own agencies, but they can also draw on the full scientific resources of the Federal government, including the United States Department of Agriculture, the National Toxicology Program, the National Institutes of Health, the National Academy of Sciences, and other similar departments and agencies. EPA and FDA are also able to use the expertise of the academic community, State and Local government officials, and public organizations.

The congressional mandate to assure the public that the levels of pesticide residues in or on food are safe is inherently and necessarily national in scope. EPA and FDA must decide what level of a pesticide residue is safe for consumption. They must make decisions which are in the broad national interest and protect the entire country, not decisions that are in the economic or political interests of a State or Local jurisdiction, or in the interest of an individual company or other special interest group. Their responsibility is to serve the best interest of consumers throughout the nation.

Food production, processing, and distribution are a truly national undertaking. USDA estimates that, in 1983, 47 of the 50 states produced principal crops valued at over $68 billion. About 25 percent of this agricultural produce was immediately exported. Most of the remaining 75 percent was shipped to more than 21,000 domestic food processers where it was prepared for the retail market. In 1980, these companies processed and sold both domestically and abroad more than 338 billion packages of food, valued at $245 billion. These hundreds of billions of individual food items have one important element in common. Their safety is evaluated, regulated, and closely monitored by our Federal government. For manufacturers to supply safe food at reasonable prices to consumers throughout the country, EPA and FDA must be able to establish and enforce a single safety standard for levels of pesticide residues in or on food.

STATEMENT OF WILLIAM J. WALSH, III
SENIOR STAFF OFFICER, COMMISSION ON LIFE SCIENCES
NATIONAL RESEARCH COUNCIL, NATIONAL ACADEMY OF SCIENCES
BEFORE THE COMMITTEE ON AGRICULTURE, NUTRITION AND FORESTRY
UNITED STATES SENATE, APRIL 30, 1986

Good morning Mr. Chairman and distinguished members of the committee. I am Bill Walsh, currently serving an EPA tour on the National Research Council (NRC). Prior to joining the staff of the NRC last November, I spent 10 years as Coordinator for Biomedical Research and Health Affairs in the Department of State's science bureau.

This statement is my own and made in response to the Chairman's request. It does not necessarily represent the views of the organizations with which I am or have been affiliated. Nor is it made on their behalf.

My statement focuses on the relationship of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to the important field of biotechnology which promises to be a $100 billion industry by the turn of the century.

FIFRA is, as we all know, a cost/benefit statute. As the regulatory agency responsible for its administration, the Environmental Protection Agency (EPA) is obliged to weigh the costs (risks) and benefits of the actions it takes to carry out its responsibilities.

The problem is that in regard to biotechnology, EPA has been looking at possible costs and benefits instead of scientifically based scientifically probable costs and scientifically probable benefits.

The purpose of my statement this morning is to propose that as you consider the reauthorization of FIFRA you consider writing into the statute that costs and benefits be determined on the basis of scientifically determined probability and not on the basis of possibility. Almost anything is possible. And, there is virtually no scientific experiment that does not have some risk (cost) associated with it.

The reason for my recommendation is that important regulatory determinations that are adversely affecting the advancement of biotechnology are being made on the basis of perceived or imagined possible risks in lieu of a realistic scientific assessment of probable risk.

I submit that regulation based on some non-scientist's perceived or imagined possible risks is bad regulation. But that is exactly what is happening. It is costing the U.S. its leadership in biotechnology. And, there is reason to believe that it is driving biotechnology research and experimentation "underground" and abroad.

To demonstrate what I am talking about, I would like to trace EPA's application of a provision of FIFRA to biotechnology and show what the consequences of that application are.

Prior to the non-scientific ravings that the deliberate release of a genetically engineered microorganism into the environment could *possibly* cause a catastrophe, the EPA permitted "small-scale field testing" of pesticides on up to ten acres of land or 1 acre of water. Everyone agrees that actual testing in the environment is crucial to a determination of the safety, efficacy, etc. of a product. The results of these tests were what EPA used to determine whether to issue and "experimental use permit" under FIFRA.

But then on October 17, 1984, EPA published in the *Federal Register* a notice, "Microbial Pesticides: Interim Policy on Small Scale Field Testing."[1] The notice states that EPA would determine whether "experimental use permits" would be required for all small-scale field tests involving "microorganisms which have been genetically altered or manipulated by humans."

In its justification for the restrictive action against biotechnology, EPA states:[2]

> "Microbial pesticides, however *may* replicate and spread beyond the site of application."
>
> "Further microbial pesticides...that have been genetically altered or manipulated by humans *may* not be subject to natural control...."
>
> "...microbial pesticides that are...genetically altered or manipulated *could* exhibit increased competitiveness...."
>
> Moreover...microorganisms...*may* be difficult to control or eradicate after being introduced."
>
> "Finally, the genetic material in some gentically modified microbes *may* be unstable or transfusable to other organisms."

Notice that the subjuctive mood and the words "may" and "could" are used throughout to express *possibilities*. There is not a single mention of a scientifically based *probability* occurring. Moreover, in the last sentence of EPA's justification for this restrictive action against testing of genetically engineered microbes, the EPA states that it does *not* have any *reason* to *believe* that any of the aforementioned *possibilities* will *occur*.[3]

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[1] *Federal Register*/Vol 49 No. 202, Wednesday October 17, 1984/ Notices p. 40659

[2] Ibid. at p. 40660

[3] Ibid: The entire sentence is:

"Although the Agency does not at this time have reason to believe that any of these conditions will necessarily occur (and thus be a cause for public concern), these factors have led the Agency to conclude on an interim basis that a closer look should be taken at small scale field tests of certain microbial pesticides."

Is this then an unreasonable regulation? In their own words, EPA had no reason to believe that any of the *possibilities* they based their justification on would occur but they brought whole areas of research and experimentation in biotechnology to a screeching halt anyway!

I am reminded of a statement made at a seminar at the Brooking's Institution in January 1985 by the former Director of NIH, Dr. Donald Fredrickson--in my opinion, one of the people most responsible for U.S. leadership in biotechnology. Dr. Fredrickson said that regulators must have the courage of their scientific convictions.

The *Federal Register* notice requires that researchers supply substantial amounts of data before EPA decides whether to permit small scale field testing. The data collection effort can be prohibitively expensive and time consuming.[4]

Perhaps the worst result of the interim policy on small scale field testing is that it has contributed to the erosion of the bond of trust and cooperation that had been built up by the RAC[5] over the years among government, academia and industry. This technology is difficult or impossible to police since many experiments can be carried out in a basement or a back yard. If unauthorized experimentation takes place, we will all lose. We will not have any idea what is going on and we will lose the benefit of the data collected in the unauthorized experiments. It would be far better if the cooperative spirit of the RAC were restored.

The interim policy on small scale field testing that was issued on October 17, 1984 is still in effect pending the imminent publication of a final policy in the *Federal Register*. Let us hope that the "final policy" regarding biotechnology will reflect costs (risks) and benefits based on *scientific probabilities*. If it is, I am confident that virtually all of biotechnology's organisms will be able to be "small scale field tested" without research stiffling regulatory procedures.

One might ask how it came about that we are basing a whole regulatory system on *possibilities* in lieu of scientifically based *probabilites*? How could we stop in its tracks a science, a technology that is so promising--not just in terms of financial rewards, employment, and the U.S. balance of trade but in terms of tremendous probable advances in human and veterinary medicine and highly probable advances in agriculture? The best answer to these questions that I have found is in an article by the eminent NIH scientist Dr. Maxine Singer which appeared in the Yale Law and Policy Review about a year ago[6].

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[4] See, for example; EPA's March 21, 1985 letter to Professors Lindow and Panapoulos and the comments of Drs. Martin and Johnson.

[5] The NIH Recombinant DNA Advisory Committee. In 1974 Scientists themselves declared a moratorium on their work in recombinant DNA until guidelines were developed. The NIH guidelines were issued in 1976 and the RAC was established as an advisory body to administer them. Industry voluntarily came to the RAC for advice beginning in the late 1970's.

In that article,[7] Dr. Singer compares Mr. Jeremy Rifkin to the Soviet agronomist, T. D. Lysenko who in the early 1930's succeeded in replacing "scientific reality" with "political ideology as the basis for Soviet policy on genetics."[8]

Dr. Singer points out that the economic consequences of Lysenko's 20 year reign were disasterous and "immeasurable."

But more ominous than the economic costs were the human, social, and scientific consequences. She points out that the Soviet Union's great geneticists who excelled in the fields of agriculture and medicine were dismissed from their positions, publicly slandered, and ridiculed. Some courageous and patriotic individuals who answered Lysenko's fantasies with sober scientific facts were arrested, tried, and deported to the gulag.

Dr. Singer continues:

> "As a result of Lysenko's persecutions, genetics essentially ceased to exist in the Soviet Union. Students were not educated in genetics. Whole generations of geneticists and biologists were lost. When Lysenko's reign finally ended in 1964, there were no classically trained geneticists, no genetics laboratories, nothing on which to build. Now, twenty years later, a country with a vast and productive scientific enterprise remains backward in one of the most vital of current fields, a field of extraordinary importance to both medicine and agriculture."
>
> "How did all this happen? How can it be that a scientifically progressive country with a great number of gifted, dedicated scientist fell into this costly morass: There were four reasons.

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[6] Singer, Maxine F., Genetics and the Law: A Scientists' View; Yale Law and Policy Review (Vol. 3:315, 1985).

[7] See also: Lysenko and Others, text of a keynote address presented at "Biotech 84" an International Conference on Biotechnology, September 10, 1984, Washington, D.C., by David Padwa, then Chairman of Agrigenetics Corporation.

[8] Singer, p. 316

> First, Lysenko himself, though a doubtful educational qualifications, was an ambitious and confident man. Second, Lysenko and his followers were able to manipulate and exploit mass public communication in the service of their ideology--for example, publishing research results in simplistic form in the popular press without peer review. Third, Lysenko substituted a simple ideology and demagoguery for a complicated reality. Fourth, Lysenko received cooperation from scientifically ignorant but politically powerful accomplices, first Stalin and later Kruschev."

I commend the entire excellent article by Dr. Singer to you. Suffice it to conclude here with my opinion that Rifkin has been successful because he has spewed forth simplistic possible scenarios of doom about a very complex science. He has put scientists on the defensive by putting them in the unenviable, impossible position of proving a negative. That is, of proving that the outrageous possibilities that he has conjured are wrong.

While there are no Stalins or Kruchevs in the U.S., Rifkin has backed the regulatory agencies into a corner by forcing them to react to lawsuits that are concerned with legalistic or, procedural errors. He then justifies his actions by repeating the pseudo-possibilities that he has conjured up. Thus, he has forced the good people in some of the regulatory agencies to base the regulation of biotechnology on possible doom scenarios instead of valid scientific probabilities.

If the United States is to maintain its leadership in biotechnology I believe it is crucial that cost/benefit analyses and the regulatory decisions they support be based scientific probabilities rather than possibilities.

Thank you Mr. Chairman for this opportunity to share these views with you.

ENVIRONMENTAL ASSESSMENT AND FINDING OF NO SIGNIFICANT IMPACT

Concerning the application to the National Institutes of Health (NIH) under the NIH Guidelines for Research Involving Recombinant DNA Molecules by Drs. Steven Lindow and Nickolas Panopoulos of the University of California, Berkeley, to field test ice-nucleation-minus bacteria prepared by recombinant DNA techniques for opurposes of biological control of frost damage to plants.

Prepared by the National Institutes of Health, Public Health Service, U.S. Department of Health and Human Services

Concurrence: James B. Wyngaarden, M.D., Director, National Institutes of Health, Date: January 21, 1985

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAR 21

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Dr. Steven Lindow
Dr. Nickolas Panopoulos
Department of Plant Pathology
University of California
Berkeley, CA. 94702

Dear Drs. Lindow and Panopoulos:

The information submitted by you and received on December 26, 1984 by EPA in response to the interim policy on small scale field testing of microbial pesticides has been reviewed. It has been decided that an Experimental Use Permit (EUP) will be required prior to your release of the non ice nucleating (INA^-) mutant bacteria into the environment.

The release of products of biotechnology into the open environment is a new and emerging technology about which relatively little is known and much is speculated. The decision to require an EUP will insure that the testing will provide the type of information needed for subsequent regulatory decisionmaking on this product, that the results of the tests will be reported to the Agency, and that sufficient oversight of the tests will be possible. The types of required information specified below to support the application for an EUP would also be supportive of future product registration. Further, while the experiments proposed would seem to pose only a very low risk of adverse ecological effects, additional scientific information must be submitted beyond that received to date to adequately support this contention. In this particular case, the Agency considers it prudent to require an EUP. However, it is anticipated that with increased knowledge and experience with biotechnology in general, the flexibility outlined in the interim policy can be more fully realized on a case-by-case basis.

The requirements for EUP applications and data to be submitted in support of EUP applications are set out in 40 CFR Parts 172 and 158 (49 FR 42856, October 24, 1984; copy attached), respectively. If you do seek an EUP, you will be required to meet the EUP data requirements of 40 CFR Parts 158.65 and 158.170 for microbial pesticides, and the additional specific data requirements described below. Note that 40 CFR Part 158.45 allows the Agency to waive data requirements on a case-by-case basis where it is determined that the requirements are not applicable to the specific case under review. Be advised that the data requirements remaining to be satisfied and those requirements which we may consider potentially not applicable to this specific case are based only upon the Agency's current knowledge and the information currently in hand. Clearly the status of these data requirements could shift with our receipt of additional pertinent information. It is the applicant's responsibility to initiate any request that the Agency consider the applicability of specific data requirements and to fully justify each such specific request for a waiver.

The following outline of the data requirements to support an EUP indicates our findings regarding whether each data requirement has been satisfied or remains to be addressed, or if that requirement may be potentially non applicable.

Part 172.4 requirements:
    172.4(b)(1) - this requirement has been satisfied.
    172.4(b)(2) - requirement for a tolerance- not necessary provided that you certify that the food or feed derived from the experimental program will be destroyed .... as outlined in 172.4(b)(2).

    172.4(b)(3)(i) - confidential statement of formula - include the name and percent by weight of each active and inert ingredient. You must also state the physical state (i.e., liquid) and density of the product (final formulation).
        (ii) - manufacturing process-additional information is required as per item 5(a) and (b) below.
        - analytical method - additional information is required as per item 4(a) below.

(iii) - residue decline data - additional information is required as per item 4(b) below.
(iv) - toxicity tests - additional information is required as per item 5(c) below. Protective clothing and equipment (respirator) label statements are required.

Part 158.170 requirements:
158.170(a) - product analysis (with the exceptions listed, all other product analysis requirements may not be applicable)
- product identity - additional information is required as per item 2 below
- manufacturing process - see 172.4(b)(3)(ii) above.
- unintentional ingredients - additional information is required as per item 5(b) below.

158.170(b) - residue data - may not be applicable provided that the crop is destroyed; see 172.4(b)(2) above.
158.170(c) - toxicology data - may not be applicable provided that protective clothing and equipment labeling statements are added.
158.170(d) - nontarget organism and environmental expression
- Tier I - nontarget plant - additional information is required as per item 3 below. The other Tier I data requirements may not be applicable.
- Tier II - terrestrial environmental testing - additional information is required as per items 1 and 4(a) and (b) below.

Product labeling must have precautionary statements addressing disposal, and use directions for application during calm (predawn) conditions using a hand sprayer developing large droplets.

The applicability of the data requirements in Part 158.170 will be considered upon receipt of your waiver request and justification. I encourage you to contact us prior to your submitting an EUP application if you have further questions about the applicable data requirements.

There are two overall issues which remain unresolved. One involves the unquantified competitiveness of the INA$^-$ mutants with the indigenous INA$^+$ populations and their ability to colonize a wide variety of plant species (e.g., newly emerging, uncolonized vegetation) particularly to the extent that INA$^+$ populations may no longer play a significant role in initiating ice crystalization on plants and on or in other media. The second issue concerns the possible effects on the survival and geographic ranges of certain plants and insects if the INA$^-$ mutants were to substantially displace the indigenous INA$^+$ populations.

If you seek an EUP these additional specific requirements should be addressed in the application:

1. additional information from greenhouse studies investigating the colonization potential on young emerging vegetation from low initial dosage of INA$^-$ mutant bacteria; while studies may exist to address this point, additional information is required on the test design, conditions, duration, age of plants, growth phase of applied bacteria and sensitivity of detection methods;

2. additional information on the identity of the INA$^-$ mutant bacteria including bacteriocin typing patterns for the parental strains and the INA$^-$ mutants; an antibiotic-sensitivity profile for the test strains; a more thorough battery of physiological and nutritional tests and morphological examination to allow comparison of INA$^-$ mutants with parental strains; additional information on the formulation to be tested including the name and percent by weight of all active and inert ingredients;

3. additional information on parental strain host plant specificity including pathogenicity to species related to snapbeans, potatoes and tomatoes and to other crops (if any) likely to be grown near the test site; further information on which native plant species are colonized by the parental strains; identification of cultivar used and procedures used in testing each host for pathogenicity;

4. additional information on detection, survival and growth of the INA$^-$ mutant including (a) the detection limits per gram of soil; information on the efficiency of recovery from soil; identification of enrichment methods used, (b) information on the survival and growth studies clarifying the experimental design, test conditions, duration, age of

plants, portion of plant tested (e.g., leaf versus blossom), time zero concentrations, and growth phase of the bacteria when applied, and (c) for proposed field monitoring clarify the number of samples to be taken per plot for each treatment and crop, and clarify the nature of the unit (substance) being sampled;

5. submission of the actual research data describing (a) construction and isolation of the INA$^-$ mutants including the molecular structure of the genome of Pseudomonas syringae strain TLP-2, (b) purity of the INA$^-$ mutants (i.e., assurance that the preparation is not contaminated with other microorganisms), and (c) temperature requirements/ survival limitations of the INA$^-$ mutants and their parental INA$^+$ strains and the information used to support the conclusion that P. syringae is not a human pathogen;

6. information on the precise location of each test site and identification of the agricultural crops likely to be found within a 1,000-meter radius of each plot; and

7. proposal of improved monitoring plans for detecting offsite dissemination (including aerial dissemination) via drift and insects (especially pollinating insects); in addition provide details of precautions used in transporting of cultures to sites and on dilution at the sites.

Regarding the proposed testing program the Agency will require a rationale to support the number of test sites if more than one site is requested. You may wish to consider proposing a phased approach wherein a minimum number of mutant strains and crops with maximum monitoring is planned initially, to be followed by more extensive testing depending upon the experience gained in the initial study. When considering a similar proposal, the FIFRA Scientific Advisory Panel indicated that they would like the testing to be done in an isolated or remote area in California. The Agency realizes that this recommendation may be problematic in obtaining meaningful, practical results, but would like you to consider this recommendation in formulating your plans. If an EUP is granted, the Agency will notify the state(s) involved through our Regional Offices. In addition, if you have not already done so, it may be to your advantage to establish direct contact with the California Department of Food and Agriculture and comparable agencies in other states regarding the proposed testing and any applicable state regulations.

Any questions concerning a poss specific data
requirements or future meetings sho red to
Mr. Henry Jacoby (703) 557-1900 wh Product
Manager for this pesticide. Your c nd understand-
ing in this matter are greatly appr

Since

Steven Schatzow, Director
Office of Pesticide Programs

Attachment

Genentech, Inc.

460 Point San Bruno Boulevard
South San Francisco, CA 94080
(415) 952-1000
TWX 9103717168

May 20, 1985

Mr William J. Walsh III
U.S. Department of State
Bureau of Oceans and International Environmental
and Scientific Affairs
Washington, D.C. 10520

Dear Mr Walsh,

I received your note and the copy of the March 21, 1985 letter from the United States Environmental Protection Agency to Drs Lindow and Panopoulos. Certainly this letter from Mr Schatzow is a prime example of how a regulatory agency of the United States Government can effectively throw hurdles in the path of a research program aimed at increasing the productivity of the land. In this case it is absurd and annoying for two specific reasons. The first is that the non-ice nucleating (INA$^-$) mutant bacteria are not microbial pesticides and yet the EPA is attempting to regulate their release as such, having simply declared in the Federal Register (Vol. 49, No. 252, 50883) that they are, in the face of clear scientific evidence to the contrary. The second point is that Dr Wyngaarden, Director of the National Institutes of Health, on January 21, 1985, signed an environmental assessment report with the finding of no significant impact of this particular study. In the face of all of this, the EPA then requests information such as a statement of the "...formula including the name and percent by weight of each active and inert ingredient including a statement of the physical state and density of the product." If that is not bureaucracy at its zenith, I am not sure what is. In addition, it is stated that "...toxicologic data may not be applicable provided that protective clothing and equipment labeling statements are added to the report."

It is clear that with such an attitude prevailing, an investigator will either lose all motivation to commence or continue a development program that may have signficant economic benefit to the United States and its citizens, or will be highly motivated to transfer the technology to another country where it might be explored and perhaps commercially developed to the benefit of that county.

You are of course aware that in this particular case, the genetically engineered INA$^-$ organism is a more stable mutant and better defined than

page two
May 20, 1985
Mr Walsh

is the naturally occurring INA bacterium which can be released into the enviornment without any regulatory oversight or bureaucratic hurdles. This is not to say that the latter needs regulation and is inappropriate; quite the contrary.

Another interesting aspect of the EPA request is that the information requested is not going to be particularly useful to the agency in making any assessment because most of the questions are not really applicable to this organism. I refer specifically to the questions about the "physical state and density of the product" and "a more thorough battery of physiological and nutritional tests in morphological examination to allow comparison of INA^- mutants with parental strains as well as additional information on the formulation to be tested including the name and percent by weight of all active and inert ingredients."

In conclusion I should hope that this request is a mistake rather than an indicator of how the United States regulatory agencies intend to deal with the development of new technologies that have considerable potential benefit to us all. I hope these comments are useful to you; I am appalled.

Sincerely yours,

David W. Martin, Jr., M.D.
Vice President - Research

Adjunct Professor of Medicine and Biochemistry
University of California, San Francisco

Member, Recombinant DNA Advisory Committee
National Institutes of Health

Lilly

Lilly Research Laboratories
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307 East McCarty Street
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Irving S. Johnson, Ph.D.
Vice President

May 15, 1985

Mr. William J. Walsh, III
Coordinator for Biomedical Affairs
Bureau of Oceans and International
Environment and Scientific Affairs
Room 4325
United States Department of State
Washington, DC 20520

Dear Bill:

In reviewing the available information regarding the recent decision of the EPA to require an Experimental Use Permit (EUP) for pending field tests of bacteria having a deleted gene affecting ice nucleation, we wish to offer the following observations and comments:

> There can never be an original experiment with zero risk. With admirable caution, the NIH-RAC has recommended approval of experiments that carefully probe new areas of application of recombinant DNA technology. The field test proposal of Drs. Lindow and Panopoulos is such an experiment. The environmental assessment prepared by NIH summarizes current knowledge about all factors bearing on possible environmental effects; we concur with the logical conclusion that no significant environmental impact should result. The EPA has requested additional information from the submitters before issuing an EUP; however, these do not appear to be aimed at any previously unknown facts about the organism or the experimental conditions that would suggest that the environmental assessment was in error. What this action does suggest, however, is that experimental field tests and other experiments involving recombinant organisms may require the collection, assembly, and submission of an inordinate amount of information in defense of protocols that, in many instances, simply duplicate in a more refined way the processes of genetic recombination that exist naturally in the biosphere.

Mr. William J. Walsh, III
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It may be appropriate to begin consideration of certain categories of recombinant DNA experiments involving release of innocuously different organisms (in terms of their defined genomic changes) as being exempt from these requirements for extensive background information based on the fact that such changes occur naturally--and often with less precision. In particular, mechanism changes in the genome of an organism which can be documented as occurring naturally such as spontaneous deletions, point mutations, transversions, transpositions, translocations, and insertions might be considered an exempt category. Also included could be self-cloning experiments, those in which the organisms can be shown not to survive beyond one season in the environment, and those which simply provide increased amounts of essential amino acids or other simple nutrients.

The question of possible occupation of an unusual ecological niche is not answered through such action; the fact to be realized, however, is that the same unanswered questions exist for organisms undergoing mechanistically natural changes. These are not uniquely the province of recombinant DNA technology. New ecological concerns are constantly being raised in a biologically dynamic world. The advisory role of the RAC is properly played when it provides recommendations bearing on the applications of recombinant technology in previously unprecedented situations.

I hope these comments will be useful to you.

With best regards,

Irving S. Johnson

ISJ/as/rl

STATEMENT OF THE PESTICIDE PRODUCERS ASSOCIATION
BEFORE THE
SENATE AGRICULTURE, NUTRITION AND FORESTRY COMMITTEE
APRIL 30, 1986

The Pesticide Producers Association (PPA) is a non-profit trade association made up primarily of small to medium sized businesses engaged in the formulation, manufacture and distribution of Agricultural Chemicals in the United States. Other trade associations may publicly state that they represent the pesticide industry, but you will understand from today's testimony that theirs is not the only view in the pesticide industry. For a majority of their business, our members rely upon the production of "generic" pesticides, those products on which the patent has expired. Our membership provides a much needed service to the Agricultural Community in securing and distributing those chemical tools necessary to allow all of us to enjoy an abundance of agricultural products at a fair and competitive price.

Today we will be concentrating our comments on business issues that are found interlaced throughout S. 2215 but most noticeably in the sections covering reregistration and inert ingredients. These business issues are not directly taken up in S. 2215, but PPA feels that in particular there is a vital need for a definition of compensation in the bill for the use of another company's health and safety data in the registration of a generic pesticide.

The PPA has been urging Congress to bring consistency to the interpretation of two business issues in FIFRA since it was passed in 1972. In 1981, we met with NACA and were able to work out a proposed compromise to both sections, 3(C)(1)(D) and (3)(C)(2)(B) of the law. The changes were approved by the House but failed to become law. PPA again initiated meetings with NACA in December 1984 in an effort to once again bring an acceptable proposal before Congress. These discussions lasted until January 1986, but were completely fruitless. In this same time frame, unknown to PPA, NACA started discussions with Environmental Groups on a compromise on FIFRA.

When PPA learned about these negotiations, we requested a degree of input, but were informed that the discussions concerned only environmental issues and that business issues were not being addressed. We have found that business issues are interspersed throughout the compromise. It is being publicly stated that the NACA/CPR compromise will be moving through the legislative process in tandem with Patent Term Restoration. Patent Term Restoration is a major business issue especially in its present Senate form where patents for pesticides will, for all practical purposes serve in perpetuity.

PPA is not trying to be an obstructionist to the NACA/CPR compromise. The issues that we are concerned with have no bearing on the environmental concerns addressed the the compromise. We are simply trying to keep competition in the pesticide industry by addressing business issues which have a direct impact upon the ability of our members to conduct business. Without changes in the data compensation area, 3(C)(1)(D) and 3(C)(2)(B), our members will be at a decided disadvantage due to these artificial barriers to generic products.

Studies have shown the anti-competitive nature of the pesticide industry (Eichers, 1980). There has been a redistribution of profits in favor of chemical producers and away from formulators and distributors (the percent of each consumer dollar going to basic chemical producers increased from 45% in 1965 to 66% in 1976). There also appears to be increasing forward vertical integration in the pesticide industry. About 50% of all formulators are now controlled by basic producers through either direct ownership or contractual obligation (Eichers, 1980, p. 13).

Even when patents expire, new entry into the market may be difficult in some cases because generic producers must register their version of the chemical with EPA for full testing. The EPA has attempted to reduce the time lag by using the data submitted by the original registrant under 3(C)(1)(D) of FIFRA. This in turn has stimulated law suits brought by the original registrants who insist on receiving compensation for the data. Such legal action can ensure that generic registrations are delayed in court for a lengthy period, effectively lengthening the life of a patent. (Butler Letter, March 20, 1986, to Senator Charles Mathias, Jr.)

The Pesticide Industry is highly concentrated with ten (10) companies controlling 66% of the world pesticide market. The U.S. market has been maintained in a fairly competitive mode due to moderate rate of turnover of leading products, allowances for generic registrations under section 3(c)(1)(D) of FIFRA, and patent expiration. However, unreasonable data compensation decisions under Section 3(C)(1)(D) are reducing new enterants into the market on non-patented pesticides. As competition in the market decreases the incentives to be innovative also decrease. This is a generally recognized empirical result of most industrial organization studies.

The NACA 1984 Industry Profile Survey shows that sales in the pesticide industry in the U.S. which include U.S. and non U.S. production was $4.33 billion in 1984 (NACA Industry Profile Study, May 22, 1985) an increase of 21% over 1983. Research and Development on the other hand submitted 18 compounds for registration in 1984 versus 11 in 1983 and total R & D expenditures in 1984 were $624.3 million versus $524.4 million in 1983 an increase of 19% (NACA Profile Study). R & D expenditures continue to climb and we see no reason for a decline because of a formula for copensation. In general costs of R & D are usually recovered within a few years if only because firms will not invest in products with low rates of returns.

We agree that the generation of data costs a great deal of money, but who actually pays for the data? Using generally accepted accounting practices, the costs of R & D is usually written off in the year the costs were incurred, up to 50%.

There is also an R & D tax credit which provides foranother 25% write off up front. This could mean that 75% of the cost of data is paid for by the American Tax Payer.

Today, technology and data are being protected under Section 10 of the present FIFRA law. The major companies would have you believe that technology is being exported by allowing the use of data for a generic registration, when in fact technology and data are being imported into the United States. The top 10 agricultural chemical companies in the world are:

Company	Country	U.S. Name
Bayer	German	Mobay
Ciba Geigy	Swiss	Ciba Geigy
Monsanto	U.S.	Monsanto
Shell	Dutch	Shell
ICI	British	ICI America
Rhone Poulenc	French	Rhone Poulenc
Dow	U.S.	Dow
Hoechst	German	American Hoechst
DuPont	U.S.	DuPont
BASF	German	BASF

The top three companies, Bayer, Ciba Geigy, and Monsanto account for 31% of the world pesticide sales. The next seven companies accounted for the next 35% of sales worldwide. This is a total of 66% of the world's pesticide sales from ten companies, seven of which are not American companies. Technology is actually coming from abroad. These same ten companies are the largest importers of pesticides into the U.S. The NACA Industry Profile Study, it states that U.S. sales on non-U.S. production increased from $497 million in 1983 to $703 million in 1984.

Reasonable compensation should be an equitable sharing of the costs of the data. In the opinion of Justice Sandra Day O'Conner written for the Supreme Court, Union Carbide vs. EPA case, Justice O'Conner stated that the court made it clear that the use of this data is not purely a private right but is more of a public right. This gives Congress the authority to allow agencies to allocate costs and benefits of regulation with Article III adjudication. Justice O'Conner called the FIFRA provision, "A pragmatic solution to the difficult problem of spreading the costs of generating adequate information regarding the safety, health, and environmental impact of a potentially dangerous product".

An equitable sharing of the cost of data is really our first issue. PPA sees a need for a legal definition of reasonable compensation for the use of data by a generic registrant under Section 3(C)(1)(D).

When a company decides to enter a pesticide market after the expiration of the patent, it must be able to determine all of its potential costs in order to make a sound business decision. It can define (1) the manufacturing process, (2) raw material costs, (3) cost of plant construction, (4) general overhead, and (5) potential market. While this information is sufficient in most businesses, there is one important element missing for a pesticide product. Data Compensation for the use of data

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submitted by another registrant to support the registration of your product, presents an unknown factor.

FIFRA provides that if one registrant relies upon data submitted by another registrant he must offer to pay compensation to the original submitter of the data. The law does not provide a definition of "reasonable compensation". If the parties involved cannot reach an agreement then either may request that the matter be submitted to binding arbitration before the Federal Mediation and Conciliation Board which is to determine "reasonable compensation" on a case by case basis.

The Act provides that the decision of the arbitrators is binding and is not appealable to the Federal courts except in cases of fraud or misconduct on the part of the arbitrators. This provision of the law was upheld on July 1, 1985, by the United States Supreme Court in the Union Carbide case. Therefore any decision of the arbitrators must be considered to be final and binding upon both parties.

The only data compensation case which has been decided by binding arbitration, to date, is Stauffer Chemical Company vs. PPG Industries, Inc. (Stauffer/PPG). The Stauffer/PPG case was heard before a panel of three arbitrators. The final decision against PPG provided for:

- PPG to pay 50% of the cost of the data relied upon by the EPA to register their product which had been submitted by Stauffer and was in the Agency's files. The data in question was valued at $2,930,000 and PPG was ordered to pay $1,465,000 to Stauffer within 30 days of the final decision. (NOTE: the data which Stauffer had submitted is not sufficient to fully register the product under Section 3 of FIFRA and will require PPG to possibly develop or replace several million dollars worth of data when the registration standard is finalized by the EPA.)
- The arbitrators ruled that PPG had gained a market advantage by not having to wait the 5 to 7 years necessary to develop the data themselves and obtain EPA registration. They also ruled that PPG had gained valuable time by relying upon Stauffer's data and had the benefit of their registered labels to copy. To compensate Stauffer for the market advantage PPG gained by relying upon Stauffer's data and labels, the arbitrators awarded them $0.15 per pound of technical produced or purchased by PPG during the 10 calendar years from 1983 through 1992. The price per pound is to be adjusted annually based on the change in the Producer price Index using November 1982 as the base year.

It is important to note that the $0.15 per pound awarded was arrived at by the arbitrators based upon a net profit by PPG of $0.60 per pound of technical. This is equivalent to 25% of PPG's net profits. No allowance was made in the decision for a drop in the net profit to below the projected $0.60 per pound. If PPG's net profit were to drop to $.30 per pound they would be paying Stauffer 50% of their net profits.

The cost of the actual arbitration process must also be considered. The fees charged by the 3 arbitrators and the American Arbitration Association (AAA) in the Stauffer/PPG case were $96,000, Stauffer and PPG split this cost with each paying $48,000. It is estimated that the legal fees for PPG in this matter would have been approximately $3000,000. The hearings lasted 20-22 days and the case was months in preparation. Our estimate of PPG's cost in this matter does not include their in-house administrative costs.

Based upon the above figures and estimates for sales contained in the arbitration decision, PPG's initial costs for data compensation and arbitration were $1,813,000 plus an additional $7,087,500 in royalty payments during the first five years of sales. If PPG's sales remain stable during the 10 year period in which royalty payments are to be made, the total cost to PPG for data compensation would be approximately $15,988,000 or 5.4 times the cost of the data involved.

Recently a second case has been submitted to the arbitrators by E.I. duPont de Nemours & Co., Inc. against Aceto Agricultural Chemicals Corporation. In this case duPont is asking:

- $3,000,000 from each of the companies or 25% of its estimated development cost for the data plus;
- a royalty of $1.50 per pound of pesticide sold containing linuron sold by the respondents during the first five years of sales.

As is demonstrated in the above two cases, it would be very difficult for a small company to decide to enter a market previously held by a major producer. The cost of such an arbitration award would be prohibitive to a small businessman. If a small businessman were successful in obtaining entry into a market, he could still be faced with data development costs of several million dollars when the registration standard for the product was issued and he was required to reregister his product. We believe that a decision such as the Stauffer/PPG decision is totally outside of the original intent of Congress when it passed the requirements for reasonable compensation 1972. We believe that the intent of this Section was to allow a company which relying upon data submitted to the Agency by another registrant to share in the cost of development of that original data, not to reward the original registrant for being the first to register the pesticide product. We contend that such rewards are the purpose of the patent laws and not FIFRA.

In addition to the anti-competitive nature of the present system of determining data compensation, a recent decision by the United States Court of Appeals has brought into question the practice of developing data necessary to support the registration of an identical prestige product prior to the expiration of a patent.

On April 23, 1984, the United States Court of appeals for the Federal Circuit handed down a decision in Roche Products, Inc. vs. Bolar Pharmaceutical Co., Inc. The Court ruled that the use of a patented product by a second party, to develop data for the purpose of obtaining an early market entry following the expiration of a patent was a violation of the "use" provisions of the law. The court held that while there as an exemption for the use of a product for "Scientific Purposes", the exemption did not apply to information used was for commerical purposes. This decision has a direct impact on the ability of a second registrent to develop data which would be necessary for the registration of a product prior to the expiration of its patent.

A certain core set of data may be required by the EPA in order to register a "Me-too" product. To prepare to enter a market on the day of patent expiration, the data would have to be prepared and submitted to the EPA at least one year prior to patent expiraion date. The restrictions on "use" of a product, such as presented in this decision, would in essence provide a patent holder at least 1.5 to 2 years of additional patent life. This wold be the time required for the second registrant to develop the minimum data necessary to register his product. It should be noted that data required to register a pesticide product is not part of the patent and has a life totally separate of the patent period.

If another registrant wished to produce the entire set of data needed to obtain a registration out of fear of an unreasonable data compensation determination, the period of time which the original patent holder would enjoy the continued monopoly in the market would be approximately 5 to 7 years.

PPA believes that the time is ripe for Congress to define by the law what is reasonable compensation for the use of another parties data. We believe that only if this is done now can Congress not only promote the development of new chemicals but also guarantee that a competitive market is established for a pesticide products thereby assuring the American consumer has an adequate and fairly priced supply of pesticide products.

PPA believes that an original data developer should receive "reasonable compensation" for the use of his data by a second registrant. We contend that such "reasonable compensation" should be determined by a definition which encompasses the following points:

1. That data has a compensable life of 15 years from the date it is first submitted to EPA; and
2. The original data developer should receive compensation for up to 15% of the original cost of the data to cover incidental costs incurred during the data development.

PPA proposes the following formula which takes in account each of these:

$$\text{DATA COMPENSATION} = \frac{\text{ACD X 1.15 X AMS}}{15}$$

Where: ACD = Actual Cost of Data
AMS = Annual Market Share of Second Registrant (Min. 5%)

EXAMPLE:

Original data submitted in 1980 at a cost of $1,500,000. Data would be compensable for 15 years until 1995. Data relied upon in 1985 by second registrant - Annual Market Share for second registrant of 8%.

DATA COMPENSATION FOR 1985 = $\frac{1,500,000 \text{ X } 1.15 \text{ X } .08}{15}$

DATA COMPENSATION FOR 1985 = 9,200

PPA contends that the original data submitter would have received reasonable compensation under the above example.

The original registrant may have had the benefit of 10 years of exclusive use of his data and even patent protection. We believe that our proposed formula provides reasonable compensation even if these were not factors.

The second issue involves the need for full industry involvement in the development of data requested under Section 3(C)(2)(B) of FIFRA to support the continued registration of a currently registered pesticide product.

Under the current provisions of FIFRA, two or more registrants may join together to produce the data necessary to support the continued registration of a pesticide product. The Act neither addresses nor provides for the mandatory cooperation of registrants in the production of this required data nor does it provide for an equitable method of cost sharing for those participants associated with the production of this data.

Our membership supports an amendment to FIFRA which would provide for:

1. The mandatory formation of industry task forces to develop the data required under section 3(C)(2)(B) data call-in notice. Such task forces would be open to any registrant effected by said data call-in notice. This part of the amendment would free up research facilities that would otherwise be doing duplicate testing; would reduce the number of man-hours the Agency would be required to expend to review the data necessary to reregister to continue the registration of existing products; would reduce total industry resources necessary to produce defensive data; reduce the number of laboratory animals necessary to answer the health and safety questions; and would enable every registrant who desires, to participate in the production and ownership of said data.
2. The immediate suspension of the registration of any registrant who refuses to join a task force.
3. The allocation of the cost associated with the development of Section 3(C)(2)(B) data should be divided among the participating registrants based on the following:
    a) The first 25% of the estimated cost for the development of the data to be divided equally among the participants with a maximum initial contribution from any one registrant of $100,000.
    b) The balance of the cost to be shared based upon the market share of each participant as determined by an independent auditor on an annual basis during the lifetime of the task

force. Each member of the task force shall be considered to have no less than a 5% market share for any given year.

4. Data developed by the Task Force shall be made available to subsequent registrants under the provisions of Section 3(C)(1)(D).

This approach to data testing will also meet the mandates of the 1972 FIFRA to conserve financial and testing resources.

Only in an open, competitive market can American agriculture be assured of a supply of agricultural chemicals which is reasonably priced and not subject to a single supply source.

The following comments on S. 2215 are based upon a preintroduction copy of the bill or upon the printed explanation appearing in the March 12, 1986, Congressional Record.

Section 201. CONDITIONAL REGISTRATION

PPA supports this section provided that changes are made to stipulate that a second registrant may obtain a registration of a similar product provided he has agreed to develop the data or to join in the development of the data when required by the Administrator.

Section 301. REREGISTRATION AND REVENUES

The time lines for Agency activity are entirely too short. One hundred eighty (180) days should be considered to be the minimum time to allow the EPA to develop its lists of products and to obtain publication in the Federal Register.

This section must be strengthened to insure that the fee for reregistration is only applied to the most basic registered active ingredients. The fee should not apply to manufacturing use only and formulated end use products produced from a registered technical.

Due to the fact that the fees would be subject to future data compensation, this section reinforces the need for a definition of "reasonable compensation".

Section 401. INERTS

PPA believes that a stronger formulators exemption should be placed into the law, especially now that inert testing appears to be a reality. The following language is offered as a replacement for the currently proposed language in Section 8 of the S. 2215 proposed amendments.

(D) EXEMPTIONS
  - (i) No applicant for registration of a pesticide who proposes to purchase a registered pesticide from another producer in order to formulate such purchased pesticide into an end-use pesticide shall be required to--
    - (I) Submit or cite data pertaining to the safety of such purchased product or;
    - (II) Offer to pay reasonable compensation otherwise required by paragraph (1)(D) of this subsection for the use of any such data.
  - (ii) No applicant for registration of a pesticide who proposes to purchase an inert ingredient from another producer in order to formulate

such inert ingredient into an end-use pesticide shall be required to --

(I) Submit or cite data pertaining to the safety of such purchased product which was required to be generated pursuant to a Data Development Plan under Section 3(h)(7) or;

(II) offer to pay reasonable compensation otherwise required by paragraph (1)(D) of this subsection for use of any such data or any other Act providing for reasonable compensation for data submitters under which the data may have been developed and submitted.

Section 510. PUBLIC RIGHT TO KNOW

To develop the fact sheets required under this section will require more than the 120 days provided. Since much of this information does not currently exist, it will have to be developed and will require at least one year.

Section 701. CANCELLATION PROCEDURES

The proposed cancellation procedures contain several points that could cause great hardship:

1. The response time for both the EPA and the registrants is too short. The period should be extended to double what is proposed for response time and for exceptional circumstances. There must be more flexibility than only 180 days.
2. Hearings may be requested by an adversely affected party, including those without economic interest. This part of the amendment can be far reaching. A person or group with out economic interest can request a hearing at any time and in all probability show cause of one type or another. The burden upon the Agencies and registrants resources would be substantial.
3. Any cancellation should only come after the scientific evidence is weighted by the Scientific Advisory Panel and if judged for cancellation, an economic impact study should be conducted because without a substitute for certain pesticides, there could be great economic harm to the farm community.
4. PPA has never believed in the automatic cancellation after five years (Section 6). The burden of paperwork and the use of resources for the small company is heavy enough without unneeded additions.

Section 801. FALSE OR INVALID DATE

While PPA supports the basic concepts of this section, we are concerned that a second registrant not be penalized for the action of the original data submitter. When a second registrant enters the market and relies upon data submitted by another data developer, he neither receives a copy of the data which has been submitted to the agency nor has the right to review such data under provisions of Section 10 of the Act. If the second registrant is held liable for the acts of the original data submitter, he would lose his registration for reasons over which he had no control.

We would suggest that a second registrant be allowed to conduct the study or studies found to be false, while still being allowed to remain upon the market under the provisions of a conditional registration.

Section 901. INSPECTION OF LABORATORIES

PPA supports this section and believes that providing the EPA with the right to inspect the laboratories conducting scientific studies to support the registration of pesticides will improve the public confidence in the Agency and in the quality of the data being used to support the registration of pesticides.

Section 1001. EXPORT OF PESTICIDES

Export of pesticides control is very difficult to be against since a majority of pesticide exports are accomplished by the major manufacturers. We do believe that only those products which are registered in the importing countries should be allowed to be exported. The safety of pesticide products should at some point be reviewed and/or approved by a responsible authority, whether is be the U.S. EPA or the appropriate body within the importing country.

If a registered U.S. EPA label is on the containers all EPA registration numbers and establishment numbers would be immediately available for all to see. These numbers must also be used on export documentation.

Section 1201. EMPLOYEE PROTECTION

PPA believes that there is sufficient protection of employees under other Federal and State laws without cluttering up FIFRA with this section.

MINOR USE PROBLEM

The Pesticide Producers Association has been attempting to address the problem of minor use for at least two years. Members of the PPA have been forced to cancel label uses or entire labels for minor use pesticides which are part of the sales tools these members have. This means that a grower of a minor use crop could potentially lose an important tool in the growing of that crop. It also means that a formulator or small producer will have less of a market for a product, thereby reducing his profitability.

PROBLEM: The problem is twofold - the loss of a minor use chemical, which is a chemical that will sell less than one million pounds per year and the loss of a major chemical used on a minor crop. Both losses are completely due to economics and directly tied to FIFRA legislation and EPA regulation. Data must be produced to prove the safety of any pesticide. The cost of the data is paid for by the manufucaturers of the technical and the formulator. The cost must be spread over the pounds of product sold. In the case of a minor use chemical, it is uneconomical to defend the product due to the inability to spread the cost of the data. This is due to the small quantities involved. A major chemical on a minor use crop presents basically the same problem. The minor use crop sales may only be $100,000 per year and the cost of the data could be as high as $100,000. This provides no fair return on the investment for the manufacturer or the formulator, neither of which should be expected to operate at a loss.

POTENTIAL SOLUTIONS:

1. Have USDA do required testing.
2. Reduces the data necessary for minor use crops
3. Reinstitute IR4 Program.
4. Design special legislation addressing the minor use problem.

1. The USDA doing the testing is impractical due to Gramm-Rudman.

2. Reducing the data necessary for a minor use crop is feasible. With a major pesticide for a minor use crop, all of the major toxicology studies will have already been completed, and many residue studies will have been done on the major crops. With Formulators Exemption and a reduction of the amount of data the formulator would have to produce, we may be able to save some of these important tools for agriculture.

3. Reinstitute IR4 Program - Because of Gramm-Rudman, the USDA has not renewed the minor use program IR4. While this program did not completely address the problem did enable several small firms to keep minor use chemicals in the field. It will be difficult to reinstitute IR4 due to Fiscal Constraints but we suggest that the program be reinstituted and made stronger.

4. Design special legislation: this must be done. EPA, in our opinion, will not act as needed without the direction of Congress. The PPA stands ready to assist in the design and drafting of this legislation.

Though the PPA approach may appear radical, we feel it is necessary for the good of our farm community. We cannot let our growers lose these important tools for growing their crops.

Mr. Chairman, we appreciate the opportunity of informing this Committee of our concerns and would be willing to answer any questions the Committee might have. Thank you for your time.

SELECTED REFERENCES

Eichers, Theodore, R. (1980) "The Farm Pesticide Industry", Washington, D.C., USDA ESCS Agriculture Econ. Report 461, September.

National Agricultural Chemicals Association - 1984 Industry Profile Study, May 22, 1985 - (Attached Exhibit I).

Butter, L. J. - Professor of Agricultural Economics, University of Wisconsin Letter and Brief to Senator Charles Mathias, Jr., March 20, 1986, (Attached Exhibit II).

Wood, McKenzie & Co., London, England - Reference Volume of Agrochemical Service, August, 1985, Private Service Report.

*Committee note: Material referred to as Exhibits I and II have been retained in the Committee files. Copies of this material can be obtained from the Committee upon request.

TESTIMONY OF DONALD H. SWAN,
Group Vice President,
Monsanto Agricultural Company,
ON BEHALF OF THE COMMITTEE FOR RESEARCH
AND DEVELOPMENT OF AGRICULTURAL CHEMICALS

April 30, 1986

My name is Don Swan, and I am Group Vice President for Monsanto Agricultural Company. I am testifying today on behalf of the Committee for Research and Development of Agricultural Chemicals, and I am accompanied by Larry D. Brady, Vice President and Group Manager of the Agricultural Chemicals Group for FMC Corporation, and John Hagaman, President of Global Agricultural Products for The Dow Chemical Company. The Committee for Research and Development of Agricultural Chemicals consists of 11 companies that invest in the research and development necessary to discover, develop, register, and commercialize environmentally acceptable and effective new pesticides for use in American agriculture.

We are testifying here today to express our strong opposition to efforts by the Pesticide Producers Association (PPA) to amend the existing data compensation and arbitration provisions of FIFRA. As you know, under the current law, a "follow-on" registrant may obtain a pesticide registration for a chemical simply by relying on data submitted by another company that has previously registered that product. Congress recognized in 1978 that these data are generated only after substantial investments of time and money. It therefore required that the follow-on registrant pay compensation to the company that submitted the data to EPA. That seems to us to make sense: the party which undertook the risks of developing data that enabled a pesticide to be commercialized should logically be compensated for a portion of the value of those data since they allow the follow-on to share in the fruits of that work. We realize that there may be disputes concerning the "value" of the data, but disagreements over the amount of compensation can be resolved by experienced, neutral arbitrators jointly selected by both parties. The arbitrators have the authority to examine the unique facts of each case and to render an appropriate decision for that case.

The FIFRA data compensation requirement is a vital element in the protection of the enormous investment that is necessary to develop and register a new pesticide. The Committee for Research and Development of Agricultural Chemicals strongly opposes PPA's efforts to tamper with this protection and believes that opening up the FIFRA amendments process to this very divisive issue will jeopardize the compromise legislation agreed to after such strenuous efforts by NACA and the labor, environmental, and consumer groups.

To fully appreciate the importance of FIFRA data compensation, it is necessary to understand the process by which new pesticide products are made available to the American farmer. The trend in the development of new agricultural pesticides is toward pesticides that are environmentally acceptable and more effective than those presently available. The benefits of such new products are obvious--more efficient food production with less pesticide usage and with fewer of the possible adverse health and environmental effects that were associated with some earlier pesticides.

But developing these new active ingredients is not an easy, fast, or inexpensive process. As a result, only a few new chemicals are registered each year. Even identifying the compounds that might ultimately be of value requires a substantial effort. Twenty years ago we could expect to find one chemical with pesticidal activity out of every 5,000 chemicals that we screened; now, we must screen 20,000 compounds to find one with pesticidal activity. Even when such a new active ingredient has been identified, there is no assurance that it will be commercially viable after the enormous amount of effort that must be devoted to developing it as a product. In addition, the regulatory scheme that enables EPA to determine that new pesticides do not pose unreasonable risks adds time and expense to the research and development costs. It typically costs a pesticide company $12 million and takes 5 years just to develop the extensive data required by EPA to support a pesticide registration. Perhaps of equal significance is the scientific expertise necessary to develop the supporting data for registration. Residue, metabolism, toxicology, and environmental fate studies require experienced, highly qualified scientists and expensive equipment to satisfy EPA's rigorous protocols. These resources are not developed overnight to satisfy a one-time need. Instead, they are developed over time as a company commercializes the results of its innovative efforts. The total investment in commercializing a new pesticide can run into tens of millions of dollars over a period of 15 to 20 years. It can take us up to 20 years or more to realize a net return on our investment.

Obviously, these substantial expenditures must occur at a stage when the product being developed is not on the market generating revenues. Accordingly, the money necessary for innovation must come from the revenues generated by previously developed products that have already been registered. Thus, if innovation is to continue, and new products to benefit the American farmer are to be available, the producer's profits from the products now on the market must be sufficient to support this major research effort. But a producer cannot generate profits sufficient to support new research and development if a follow-on company can quickly obtain its own registration for the producer's successful and proven product by relying on the producer's data without paying a fair share of the investment required to register the product. When that occurs, there is such a disparity in costs between the original producer and the follow-on registrant that the original producer simply cannot earn enough on its product to support research and development of new products for the future.

This "price squeeze" is aggravated by the erosion of patent and other protection that might otherwise be available. Because of the substantial time that it takes to develop and register a product, the seventeen years of market protection contemplated by the patent laws are reduced by the 7 to 8 years typically necessary to develop required data and complete EPA review of a registration application. Although patent term restoration legislation has been proposed to address this problem, no such protection is currently available. Any legislation that is enacted will be only prospective and will not protect investments in existing products. Similarly, the "exclusive use" provision included in FIFRA in 1978 is available only for products first registered after September 30, 1978 and thus is completely unavailable for the vast majority of pesticides for which compensation is now an issue. Thus, the existing compensation scheme is an extremely important part of the protection necessary to continued innovation in agricultural pesticides.

Why, then, has PPA proposed to tamper with these provisions? We believe that, when the arguments advanced by PPA are examined in light of the facts, they do not justify the rigid, de minimis formula advanced by PPA. We are thus forced to conclude that PPA's real objective, now that the compensation provisions have begun to be implemented and follow-on registrants have for the first time been forced to begin bearing a fair share of data costs, is to avoid responsibility for paying meaningful compensation to the original registrant for the value of the investment required to develop the data to support registration of products from which they seek to reap substantial profits.

One argument frequently advanced by follow-on registrants is that FIFRA compensation provisions benefit big producers to the detriment of small producers, and that minimizing compensation is necessary for the "little guy" to compete in the pesticide business. This simply is not true. Data compensation is an issue between data developers and follow-on companies, not between large and small companies. Most of the "little guys" in the business are formulators who qualify for the FIFRA formulator's exemption and who are not obligated to pay data compensation at all. The companies that do not qualify for the formulator's exemption but that obtain follow-on registrations on the basis of other companies' registration data are, in many cases, quite large themselves; some are larger than the basic producers. Others are backed by large foreign suppliers. In either case, they are well able to support a fair share of the investment required to generate the data needed to assure the public that pesticides will not pose unreasonable risks.

A related argument advanced by PPA is that arbitration results in awards that, in PPA's view, are excessive. In fact, there has been only one large compensation award and that involved an arbitration where the follow-on registrant was three times as large as the basic producer. Two other arbitrations have resulted in settlement agreements, and two compensation decisions by EPA under the previous version of FIFRA resulted in very small compensation awards to the data submitters.

Another argument that PPA relies on is that follow-on registrants want "certainty;" they want to know at an early stage exactly what their costs are going to be. The companies that develop new pesticides have no such certainty; when we start down the long road of developing a new product, we do not know what the total cost of that development will be or whether the product will ultimately be successful enough for us to recover those costs. Moreover, there are mechanisms by which follow-on registrants can determine their costs with greater certainty at an earlier stage if that is what they truly wish to do. The companies can, of course, generate their own data rather than relying on the initial registrant's data. Even if a follow-on registrant wishes to rely on our data, however, it is important to note that FIFRA authorizes either party--the data submitter or the follow-on--to initiate arbitration. A follow-on registrant that sincerely desires to determine its costs can initiate arbitration itself at any time starting ninety days after it sends its compensation offer to the data submitter. This would allow a follow-on registrant to know with certainty what its costs will be before it commences manufacturing.

PPA has also argued that compensation somehow extends the patent protection available to innovating companies. This argument reflects a fundamental misunderstanding of the different purposes of the patent laws and FIFRA data compensation. Patents provide the right to prevent others from marketing the patented products, while data compensation protects investments in underlying research data. If you run a manufacturing business and you invent a successful new product, you would expect other companies to enter the market to compete with you once your patent expires. However, you would not expect them to have the right to come into your plant and have the benefit of your blueprints, research data, or other proprietary information--at least not without paying you for the value of that information. That is what FIFRA data compensation requires. Unlike a patent, it does not prevent our competitors from entering the market, but it does require that if they do so on the basis of our work and effort, they must compensate us.

Other arguments advanced by PPA are similarly without foundation. The Roche Products v. Bolar

Pharmaceutical case cited by PPA is a patent case that has nothing to do with the compensation and arbitration provisions that PPA seeks to change. Nor does the lack of a comparable compensation provision for pharmaceuticals under the Food and Drug Act suggest that compensation is inappropriate under FIFRA. The pesticide and pharmaceuticals industries are very different. The markets for drugs are much larger than pesticide markets; drugs, unlike agricultural products, have few acceptable alternatives and are frequently prescribed by physicians. Finally, drug markets are protected by a patent term restoration law. The drug markets therefore offer far more opportunities for innovators to recover their development investment.

In short, the data compensation provided by FIFRA is critical to innovation in agricultural pesticides. The current arbitration scheme, which permits neutral, experienced arbitrators to tailor compensation awards to fit the facts of each individual case was devised precisely because Congress in 1978 was unable to develop a fixed compensation formula that would be sufficiently flexible to be fair in the wide variety of circumstances that can arise. The system is beginning to work and should be allowed to continue.

STATEMENT OF MAUREEN K. HINKLE, DIRECTOR, AGRICULTURAL POLICY, NATIONAL AUDUBON SOCIETY

Mr. Chairman and members of the committee, on behalf of the National Audubon Society (NAS), the Environmental Defense Fund (EDF), and the Defenders of Wildlife (DOW), we are pleased to present testimony before this committee as you consider substantive amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Our organizations have established a consistent record of involvement in governmental pesticides policy going back to 1971. EDF and Audubon were instrumental in the 1972 enactment of FIFRA, and all three groups actively worked on amendments to the Act in 1975 and 1978. Moreover, all three organizations have participated in EPA administrative hearings under FIFRA's section 6, as well as being active in the implementation phase of the mandated provisions of FIFRA. We have also commented on special reviews, and Audubon and Defenders participated in negotiated rulemaking on EPA's emergency exemption regulations last year.

Ever since pesticides regulation was transferred from USDA to the Environmental Protection Agency, the program has been treated as a kind of stepchild. Through the years, pesticides regulation at EPA took a back seat to air and water regulation and more recently to hazardous waste disposal. Yet pesticides are as toxic substances as many hazardous wastes, and are widely and/or intentionally introduced into the environment where they may, or may not, stay where they are needed and do only as intended.

Part of the problem in pesticides regulation has been the FIFRA itself which, even in its amended forms, has proven inadequate to its tasks. This past year parties with widely varying interests in FIFRA worked together to negotiate a compromise bill, which though by no means perfect, has scoped out many problem areas in pesticides regulation. Congress was thereby provided a head start by the agreement on needed changes in FIFRA embodied in S. 2215, produced after bargaining between many consumer and environmental groups and the National Agriculture Chemicals Association.

We commend the environmental and industry officials participating in this cooperative exercise on their commitment over the previous year to as much agreement as possible on amendments necessary for FIFRA. The product and associated materials reflect a great deal of effort and dedication, and the outcome lays valuable groundwork for improved regulation. The involvement of a vast number of groups heretofore not participants in pesticides regulation is particularly encouraging. Pesticides policies affect society at large in beneficial as well as harmful ways, and greater involvement by such groups in pesticides regulatory decisions is essential if the public is to be adequately protected. EPA's decision to give the highest priority to the pesticides program in its current ranking of areas of its responsibility requiring particular attention will also serve to improve the quantity and quality of pesticide decisions.

The coalition agreement is not, however, a major overhaul of FIFRA in the way the 1972 amendments reformed the 1947 Act. There were major amendments in 1975 and 1978, too, in traditional hearings with input from all relevant parties. In 1981 environmentalists asserted, and in 1983 industry insisted, that FIFRA did not need to be changed -- that problems stemmed from implementation. Although it is arguable that FIFRA's basic structure is acceptable at least some of the time, there is at this time universal agreement that Congress needs to make FIFRA work in a more timely way.

Our testimony today analyzes proposals developed by the Reform Coalition (S. 2215). We did not participate in the negotiations, enabling us to comment on the merits of the resulting proposals for legislative change without the customary constraints placed on a negotiating party.

It also addresses aspects of S. 2346, introduced by Senator Helms. This bill is in many respects a regression from current law in our eyes, however. Rather than detail a lengthy criticism of it, we urge the Committee to reject S. 2346 except for those provisions that offer an improvement over the current law.

Our statement addresses those provisions of the coalition proposal (S. 2215) that we support and includes provisions of S. 2346 which we support also; provisions that we believe need to be incorporated and the issue of who can initiate cancellation hearings, the single most important problem in both proposals, we address subsequently A final section discusses deadlines, and the need for them to be tight but realistic.

I. Provisions of S. 2215 and S. 2346 which are nearly identical and which we support:

1. Pre-registration access to health and safety studies is permitted by EPA to the public under prescribed conditions. [Sec. 101 of S. 2215, Sec. 208 of S. 2346]

2. Export notification of voluntary and withdrawn chemicals to receiving countries would be included, and affirmative disclosure is also required. The requirements may be cumbersome, but are more comprehensive than current law. [Secs. 1004-6 of S. 2215, Secs. 1301-3 of S. 2346]

II. Provisions of S. 2215 which we support:

1. Data gap requirement. Currently data gaps tend to favor pesticides for which no data are available; this provision would hasten evaluation. [Sec. 301 and 302 of S. 2215]

2. Community right to know. Local communities would be able to learn of toxicity and other information on pesticides produced in their neighborhood. [Sec. 501 of S. 2215]

3. Provision is made for revocation of tolerances on imported commodities which would halt the "boomerang" aspect of pesticide exports. [Sec. 1007 of S. 2215]

4. Provision for anti-retaliation employee protection adds to FIFRA what exists in other laws for employees participating in administrative proceedings. [Sec. 1201 of S. 2215]

5. Re-registration fees are mandated to help pay for EPA's evalu-

ation costs. [Sec. 302(g)(10) of S. 2215]

III. Provisions of S. 2346 which we support:

1. Authority of states: Sec. 1702 of S. 2346 amends Sec. 24(c) of FIFRA by providing for automatic deletion of special state registrations by notice rather than current burdensome cancellation procedures. State registrations under 24(c) are sometimes not used, expire, or are otherwise removed from the books. When state agencies requested this provision three years ago, Audubon and the National Wildlife Federation agreed with the need for such a change.

2. Inspection of establishments and warrants: S. 2346 extends the power of inspections to distributors, testing facilities, and places where pesticides are sold, packaged or labeled. Thus it is more comprehensive than the inspection authority proposed in S. 2215 which only extends to laboratories in connection with experimental permits and registration. S. 2346 also prescribes procedures to protect parties that are inspected, [Sec. 703] and Sec. 704 provides for coordination with other agencies involved in inspections. Audubon, EDF, and Defenders support all of Sections 701-4 of S. 2346.

3. Penalties: S. 2346 would double civil penalties and would count each day such violation continues as a separate offense. Such a provision is overdue, and necessary. Penalties, however, are still too low to constitute a deterent, particularly in comparison with the $100,000 fine and three years imprisonment imposed for information disclosure in both S. 2215 and S. 2346. We support Sections 1101 and 1102 of S. 2346 which would apply criminal penalties to testing facilities as well as registrants. The criminal penalty of $2,000 is far too small compared with the $100,000 penalty for "knowing violation" of disclosure. Either the $100,000 disclosure penalty should be reduced, or the $2,000 criminal penalty should be increased to the higher amount. Imprisonment for knowing violations of EPA regulations or falsification of data should also be added.

4. Other unlawful acts: We support Sec. 1002 of S. 2346 (except for a change in Sec. (8)(Q) to bring it into line with other statutes). As a whole, Sec. 1002 provides clarifying corrections in the law and provides much-needed protection for the public-at-large.

   The changes we would suggest for the first new clause, Sec. 8(Q), are as follows:

   (Q) To knowingly or willfully falsify all or part of any data submitted pursuant to this Act, or to knowingly or willfully submit such false data;

We entirely support clauses (R) through (U) for the following reasons:

(R) Makes it unlawful to violate regulations prescribed for good laboratory practice standards;

(S) If a permitee disregards the terms of a section 18 emergency exemption, he could be prosecuted. Currently permitees may only have their authority to use the violated exemption withdrawn.

(T) Misrepresentation regarding *any* ingredient, metabolic or degradation product, protocol, procedure, opinion, etc., to the agency should be unlawful. In the past, refusal to admit *awareness* of a harmful degradation product was not *specifically* unlawful, and harmful degradation products have been discovered by EPA or independent scientists many years *after* the manufacturer knew of their presence. Audubon, EDF, and Defenders of Wildlife cannot emphasize strongly enough the importance of this provision, particularly in view of the trend to recycle old chemicals by substituting one molecule and calling the result a "new" chemical. These are then treated as if there were no data on potential impacts, despite the fact that breakdown products are the same as those of the *copied* product.

(U) Violations of regulations should apply to commercial applicators *as well as* to those who apply pesticides commercially since not all *who are paid* to apply pesticides are *certified*.

IV. *Additions or changes to be incorporated:*

1. *Data disclosure to states* should include sharing with foreign countries when in the national interest (bilateral treaties with Canada for example). [Sec. 601 of S. 2215]

2. *Inert ingredients*. Both S. 2215 and S. 2346 propose listing procedures [Secs. 401-408 of S. 2215; Secs. 212, 213, 214 and 801 of S. 2346] which would effectively delay what the agency has already put in place. The rotations on and off lists and the protocols are unnecessarily cumbersome. Congress does not need to replicate the complexity of section 307 of the Clean Water Act in regulating inerts under FIFRA.

In view of EPA's identification of 55 inerts of immediate toxicological concern and a comprehensive policy strategy to evaluate and regulate inerts, *the only necessary legislative change* is a provision to *mandate disclosure* on the product label of hazardous inerts as well as *any* biologically or chemically "active" ingredient. This is *extremely important* because some designated inerts are *active* ingredients (AIs) in *other* formulations, and *active* contaminants have found their way into formulations through failure of conversion from intermediates or through the manufacturing process. Regardless of *how* these toxicologically active substances remain in the *final* product, if they are identified, they need to be disclosed on the label.

V. *Provisions not included in either S. 2215 or S. 2346:*

Indemnities. Good public policy requires Congress to strike section 15 of FIFRA, which provides for indemnities to pesticide companies for stocks of suspended products. $15 to 20 million was paid for stocks of silvex in 1982, and $2.5 million was provided for suspended stocks of EDB in 1984. Taxpayers should not have to compensate companies for acquiring excess stocks of substances whose risks have been known and documented for several years. This should be a risk borne by the registrant and serve as a deterent against stockpiling pesticides whose safety is questioned -- now the incentive runs just the other way since if suspended, taxpayers will in effect buy all existing stocks. If a product is truly suspended without advance warning, out of the blue so to speak, Congress can enact special legislation as it did for tris-treated pajamas in 1976. In this day of Gramm-Rudman-Hollings, it does not make sense to force the Treasury to pay out millions of dollars for bad marketplace decisions by risk taking pesticide manufacturers.

VI. Change in who can initiate cancellation and suspension hearing procedures:

The most important procedural issue in FIFRA for our groups in this decade has been the right of citizen groups to challenge agency decisions not to cancel uses of a pesticide on the grounds that continued use poses a substantial question of safety. Neither S. 2215 nor S. 2346 provides for the right to a hearing under such circumstances. Because of the experience of our respective organizations in cancellation hearings, we see a compelling need to resolve several problems inherent in these procedures.

Background: Throughout most of the decade of the 1970s, EDF and Audubon played an active part in EPA's pesticide decisionmaking process. With regard to several pesticides that proved uncontrollable once released into the environment (DDT, Aldrin/Dieldrin, Chlordane/ Heptachlor, and Mirex), environmental groups provided scientific information and other predictive data that helped the EPA administrator to make his cancellation decisions. A 1980 court decision, however, greatly restricted the role that groups could play in the pesticide process; this decision was based solely on an interpretation of section 6(b) of FIFRA and did not purport to consider the desirability from a public policy standpoint of allowing citizen groups to request hearings regarding EPA pesticide decisions. Environmental Defense Fund v. Costle, 631 F.2d 922, 932-37 (1980), cert. denied, 449 U.S. 1112 (1981). That decision held, in summary, that while pesticide registrants could request a hearing to challenge an EPA decision to restrict a pesticide, environmental and consumer or farm worker groups were not intended by Congress to be able in parallel fashion to request a hearing when the agency refused to restrict a pesticide. Instead, these latter groups were to go to a district court and, with the burden of proof, convince a judge EPA was wrong, defend that decision in an appellate court, and then return to the agency to do it all over again. Obviously this cumbersome, time consuming and expensive process ,is unworkable, and indeed has effectively barred consumer and environmental groups from meaningful challenge of EPA pesticide decisions ever since.

Provision for standing by citizen groups to request a hearing with regard to an administrator's decision not to regulate a pesticide would do nothing more than restore the status quo ante, making it clear that -- whatever the validity of the Court of Appeals' 1980

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interpretation of FIFRA -- Congress now believes that citizens and citizen groups can make important contributions to EPA's pesticide decisionmaking process. The question whether to cancel a pesticide is not one that can be resolved by simple notice and comment fact-finding procedures; it is an attempt, not simply to discover past facts, but to predict likely effects, to make tradeoffs between ecological and human health considerations on one side and economic and food supply considerations on the other. The decisions must be made in the presence of scientific and economic uncertainty, and one goal of the hearing process is to narrow as much as possible the range of uncertain variables with which the administrator must contend. Cross examination of proponents of data is critical to probe for uncertainties and to illustrate where fact ends and value judgments begin.

For these reasons, it is particularly critical in the pesticide context that citizens and citizen groups have standing to request a hearing when the administrator decides not to take cancellation action with regard to a pesticide, just as it is important that a pesticide manufacturer have standing (as it does under present law) to seek a hearing when the administrator indicates that he believes cancellation is warranted. In both cases, the public is best served by a full airing of all points of view and a full presentation of all available evidence before a final decision is reached. In addition, hearings on pesticide issues serve the due process goal of allowing all citizens a right to be heard before decisions affecting them are made by their government, thereby establishing greater acceptance of the resulting decision.

The importance of greater public participation in EPA pesticide proceedings is underscored by a recent recommendation of the Administrative Conference of the United States. The Administrative Conference is a permanent, independent agency of the United States Government, and its governing council presently includes a number of officials of the Reagan Administration. On June 18, 1982, the Administrative Conference adopted a recommendation with regard to "Federal Regulation of Cancer-Causing Chemicals," and this recommendation strongly endorses public participation in decisions like those regarding pesticides, for reasons relating to fairness, accuracy, balance, and the acceptability of agency decision. This recommendation from an agency highly respected for its administrative law expertise should be considered as you consider FIFRA amendments.

Legislative language: Standing to request a hearing to challenge an EPA decision not to restrict a pesticide could be resolved by adding the underlined word and striking out the last five words in the current FIFRA Sec. 6(b)(2) "(ii) a request for a hearing is made by any interested person ~~adversely affected by the notice~~." Or an appropriate change in S. 2215 could be: Sec. 704. HEARING FOLLOWING INTERIM ADMINISTRATIVE REVIEW -- (2) REQUEST FOR HEARING. -- Following an interim administrative review, any person may request a hearing within 30 days of such decision or failure to make a decision. (This revision essentially strikes "who is adversely affected by a decision . . .") Further, it should be made clear that the necessary "interest" need not be economic, but might also include concern for safety and for environmental protection.

Rationale: Fear of frivolous citizen suits costly to EPA and registrants alike, the chief argument offered against the above discribed reform, is unwarranted. Cancellation hearings are lengthy, time consuming, and costly for all concerned, citizen group participants included. There is little likelihood consumer, farm worker, or environmental groups would request a hearing without good reason, and unless they were willing to stay with the hearing process until the end. Therefore hearing requests by these groups would be rare, but the existence of the right to ask for a hearing to challenge an EPA decision not to regulate more strictly would serve as an incentive to the Administrator to make such a decision carefully, just as the registrant's current hearing right to challenge what it feels to be an overbroad and restrictive decision makes an Administrator think twice before suspending or cancelling a pesticide.

Further, in hearings called to challenge an EPA decision not to further restrict use of a pesticide, while those challenging EPA should have the burden of making a *prima facie* case that EPA was wrong, that showing having been made, the ultimate burden of proof should then return to the registrant to prove beyond a reasonable doubt the safety of its product -- a burden of proving safety the existing case law at all times places unambiguously upon the registrant. This is not only because the registrant has the best access to the data, but also because, under FIFRA"S "test first then use" philosophy, it is the registrant who proposes to alter the *status quo* and, for his profit, put the pesticide into the environment.

Rulemaking: There is increased interest in streamlining the suspension/cancellation hearing process, while retaining current procedural benefits such as cross examination. We regard EPA's April 22, 1986 discussion on the subject of hybrid rulemaking, contained in its House Agriculture Committee testimony, as a fair and efficient approach to reducing EPA's adjudicatory burden, combining only what is necessary from the adjudicative rulemaking model with notice and comment rulemaking,

Hybrid rulemaking offers benefits for all concerned as an alternative for certain situations. Standing would be resolved for such purposes since everyone would be eligible in principal to participate who presented a position-comment in the "RPAR" special review proceeding. The Administrative Law Judge would, as now, adopt procedures to prevent an overly long and complicated proceeding, perhaps by requiring allied parties to proceed as one. The RPAR record is a ready-made official central hearing record. Cross examination should be afforded, but might be limited, for example, in time and scope. Mechanisms for discovery already exist, and include FOIA for members of the public, and section 3(c)(2)(B) for EPA to require needed data from the registrant. In addition to these existing mechanisms, the rules of discovery as modified by the Administrative Law Judge should ensure that existing relevent data is obtained from other federal agencies, the states, users and the registrant. These mechanisms are already utilized in registrant-requested hearings alleging overly restrictive proposed regulation; they would serve just as well in hearings requested by those with other than an economic interest.

VII. Deadlines:

We share the frustration with EPA's inexcusable slowness in registering and regulating pesticides. At the same time, the record should be viewed in context. EPA's predecessor, USDA, was such a failure in pesticide regulation (as opposed to pesticide promotion), that the authority to regulate pesticides was transferred to EPA after virtually nothing was done by USDA in twenty years. After FIFRA was overhauled in 1972, EPA was forceful in cancelling a number of widely used pesticides. To name a few, cancellation of DDT in 1972, Aldrin/Dieldrin in 1975, Chlordane/Heptachlor in 1976, Mirex in 1978, 2,4,5-T in 1982, and EDB in 1983. RPARs on a great number of chemicals have also resulted in restrictions on many uses, voluntary cancellations of carcinogenic pesticides such as BHC in 1976 and toxaphene 1983, and more intense scrutiny of existing chemicals.

The two bills being considered seek to cure regulatory delay, particularly in filling of data gaps, by imposing tight deadlines. The underlying premise is that reregistration fees will pay for the additional resources needed to meet the mandated deadlines.

Yet it is also true that when an agency is jammed with unreasonably short procedural deadlines for an "assembly line" listing of technical risks to check off, only cursory examination of the data is possible and rubber stamping of inducing submission is certain. Many real and substantial risks will surely go unaddressed, lost in the press created by tight time limits. Rapid, automatic registration is clearly not protective of the public; neither does industry need routine and indiscriminate evaluation of its data produced at such cost. Adequate review better assures sustained marketability of pesticides since problems can be identified in advance, and appropriate restrictions imposed to prevent "surprise" disasters, thereby protecting the public and industry alike.

We think it an open question whether the deadlines set by the coalitions are realistic for EPA to meet even if it had adequate resources. What the deadlines should be is an important decision for the committee. We respectfully request that the deadlines set for the agency be made a special cause of inquiry for the Committee. The should be made realistic and helpful so that priorities can be established and the goal of environmental protection can be met. Reasonable deadlines are valuable and need to be set to prompt the agency to act more efficiently and forcefully. Unreasonably short deadlines, however, just ensure slapdash work and rubber stamp approvals.

Above all, resources for EPA on pesticides must be assured in advance, before starting the clock on any set of specific deadlines. As stated, we support the concept of fees mandated to pay for EPA's evaluation costs contained in S. 2215 (Sec. 302(g)(10)). In order to accomplish the goal of accelerating the pace of reregistration, however, sufficient revenue must be assured and provided to EPA up front. Much of the cost of pesticides regulation revolves around applications for expanded uses of a registration, each separate use constituting a "new" registration. In order to cover the costs, each "new" registration could involve a "licensing" fee to recover at least the costs of the paperwork. Otherwise, to set tasks without providing the necessary resources is cynical folly, doomed to failure from the start.

Conclusion

Mindful of the limited time left on this legislative calendar, and in the interest of narrowing the FIFRA amendments to those that are essential and helpful at this time or agreed upon by diverse interests, Audubon, EDF, and Defenders urge the Committee to approve the following provisions:

1. Standing for interested citizens to request a hearing with regard to an agency decision not to cancel uses of a pesticide, (p. 6 of this testimony) with the requisite "interest" not limited to economics.
2. Simplifying procedures for cancellation hearings as outlined on p. 7 of our testimony and pp. 13-14 of EPA's testimony.
3. Strike indemnities for suspended stocks, pp. 4-5 of this testimony and p. 23 of EPA's testimony.
4. Unlawful acts section with added words in false data submission (Secs. 1101 and 1102 of S. 2346).
5. Inspections authority (Secs. 701-704 of S. 2346)
6. Disclosure of hazardous inerts and any active ingredient on labels. (strike most of S. 2215 and S. 2346 on inerts)
7. Registration and reregistration fees (add registration fees to S. 2215)
8. Elimination of data gaps within realistic deadlines for doing so (S. 2215 with changes in schedule)
9. Community right to know (S. 2215)
10. Data disclosure to states (add foreign countries (Sec. 601 of S. 2215)
11. Employee anti-retaliation protection (S. 2215)
12. Preregistration access by public to health and safety data (S. 2215 and S. 2346)
13. Export notification (with clarification, as in S. 2215 and S. 2346)
14. Authority of states to delete unused 24(c) registrations (Sec. 1702 of S. 2346)

Essentially these changes would accomplish the following beneficial effects:

1. Improved regulatory efficiency: Nos. 1, 2, 8, 10, and 14.

2. Improved public trust: Nos. 1, 2, 5, 6, 9, 11, and 12.
3. Deterrence of irresponsible acts: Nos. 4 and 5.
4. Lower cost to/outlays for U.S. Treasury: Nos. 3 and 7.

Thank you for this opportunity to present our views.

STATEMENT OF ELLEN HAAS, EXECUTIVE DIRECTOR, PUBLIC VOICE FOR FOOD AND HEALTH POLICY

Chairman Helms and members of the Committee, good afternoon. I am Ellen Haas, Executive Director of Public Voice for Food and Health Policy, a non-profit consumer research, education and advocacy group concerned with food, nutrition and agriculture issues. We are pleased to be before you today to provide you with our thoughts on the bill, S. 2215, a bill that would create greater public protections from residues of inadequately tested pesticides--pesticides that permeate our nation's food supply.

We praise this compromise legislation which is the proud effort of 41 consumer, environmental and labor organizations and 92 chemical companies. We strongly support the amendments proposed in S. 2215, because they will provide some much-needed, critical improvements in the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"). These are changes that will lead to a reduction of the risk to public health posed by the widespread use of pesticides in agriculture products.

Public Voice for some time has monitored and challenged the problems of pesticide control in this country and the difficulties the Federal government has had in controlling the pesticides that present hazards to the environment and to human health. "Harmful Pesticide Residues on Fresh Produce" was one of ten key areas targeted for reform in our 1983 report, "A Market Basket of Food Hazards: Critical Gaps in Government Protection".

Many serious public health problems in recent years continue to be caused by pesticides--including California's recall last summer of watermelons tainted with aldicarb, and the recalls last month in Arkansas, Kansas, Mississippi, Oklahoma, and Tennessee of thousands of gallons of milk contaminated with the suspected carcinogen heptachlor.

The true safety crisis in pesticide residues, however, is not as well-publicized as with these kinds of highly conspicuous poisonings. Pesticide residues at present generally pervade the food supply as an invisible danger. The Environmental Protection Agency ("EPA") estimates that 1 billion pounds of pesticides a year are used in domestic farming--that amounts to over four pounds of pesticides for each and every American.

Consumers who purchase food in the marketplace simply cannot protect themselves from harmful pesticides without strong government involvement. Consumers have no easy way of identifying which pesticides have been used on their fruits and vegetables. Consumers cannot see, smell or tase any lingering pesticide residues. And consumers are concerned that current government procedures do not afford them adequate protections from undetermined chemical hazards.

Consumers rate the issue of pesticide residues in food as the most significant food safety problem, according to the Food Marketing Institute's soon to be released 1986 survey of public attitudes, Trends - Consumer Attitudes and the Supermarket. 75 percent of those polled believed that pesticide residues are a serious health hazard. This consumer anxiety about pesticides in foods is justified. According to a National Resources Defense Council analysis of fresh produce in San Francisco supermarkets, 44 percent contained measurable residues of one of nineteen different pesticides and 42 percent contained more than one chemical residue.

Unfortunately, because of these residues, consumers are routinely exposed to potentially significant health risks. Many pesticides in use have either been inadequately tested or have actually been found to be hazardous. In the words of Lewis

Regenstein, in his book, America the Poisoned, "the ultimate victims of our pesticide folly are not the insects, but ourselves." He cites the President's Council on the Environmental Quality as saying, "Pesticide residues are common in U.S. food and water...the effects of long-term, low-level dosages have not been adequately studied...heavy pesticide use in southeastern U.S. cotton and vegetable crops was associated with human cancer mortality."

A 1982 study by the House Committee on Agriculture confirmed that there is an astounding dearth of adequate health data: 84 percent of registered pesticides lack adequate cancer tests, 93 percent lack adequate genetic mutation tests and 70 percent lack birth defects tests. Consumers cannot, therefore, be assured that the pesticide residues in their food products are harmless.

S. 2215 takes giant strides forward in improving the status quo. The bill will remedy many notable weaknesses in the current regulatory program. S. 2215 will:

- spur the EPA to develop an efficient schedule for registration of pesticides with lists of priorities
- require data to support reregistration
- create a revenue pool to assist EPA in its responsibilities
- establish expeditious EPA review and regulatory action on registrations that are based on invalid or faulty data
- increase public access to health and safety data submitted by industry by permitting public perusal of such information prior to EPA action on registration
- provide increased EPA authority to regulate inert ingredients in pesticides
- require EPA to take action against a pesticide when there is concrete evidence of harm
- enable local citizens to learn of pesticide production in their neighborhood through an innovative community right-to-know provision

Public Voice believes these changes will be beneficial to the consumer and all those involved in pesticide application. Consumers will be able to expect safer produce in the supermarkets as a result of better health data for pesticides and improved EPA registration procedures. S. 2215 should be passed by Congress as swiftly as possible.

STATEMENT OF MICHAEL C. FARRAR, VICE PRESIDENT, NATIONAL FOREST PRODUCTS ASSOCIATION

The National Forest Products Association (NFPA) welcomes the opportunity to comment on S. 2215, the work product of the negotiations between the National Agricultural Chemicals Association (NACA) and the coalition of environmental, labor, and consumer groups called the Campaign for Pesticide Reform (CPR). The forest products industry commends the efforts of NACA and CPR in working out a compromise covering some of the areas which have proved stumbling blocks to FIFRA amendments in recent years.

Nonetheless, NFPA is particularly pleased with the introduction of another bill, S. 2346, which responds to the interests and needs of a third group affected by FIFRA--the users of pesticides. NFPA is concerned that the NACA/CPR bill could seriously affect the ability of the forest products industry to maintain the use of safe pesticides, and even more importantly, could reduce our access to new pesticides which may be safer or more effective. With the introduction of S. 2346 by Chairman Helms, we believe reasonable options for addressing these concerns are now available for the Committee's consideration.

NFPA's comments on each of the bills, S. 2215 and S. 2346, are presented below. NFPA urges the Senate Agriculture, Nutrition, and Forestry Committee to pursue FIFRA amendments vigorously in 1986, but to be sure to consider the concerns of pesticide users in that process.

INTRODUCTION: THE BASIS FOR THE FOREST INDUSTRY' CONCERNS

Pesticides are an important part of modern forest management. Where they are needed, pesticides can double forest productivity. In some cases after harvest, it would be impossible to establish a new productive, commercially valuable forest without pesticides. Although they are vital where needed, pesticides are used on only an extremely small percentage of the nation's forests. Even where needed, forestry applications typically call for low concentrations of pesticides no more than three times during the 30 to 80-year growing cycle of a forest. For these reasons, forestry represents only a small potential market for pesticide producers.

As a result, the forest industry must rely on using pesticides developed for other markets--the forestry market alone does not justify the research, development, and registration costs which can exceed $40 million for a single pesticide. Because only a handful of the nation's largest crops offer a sufficient market to justify research into new pesticides, the smaller pesticide users must rely on pesticides developed for other markets. But as new pesticides are developed, farmers growing the major crops begin to turn to them. The older pesticides remain important only to the smaller, fragmented user groups. All too frequently these user groups are not significant enough in terms of market to convince the registrant to expend substantial resources to protect their uses.

FIFRA legislation and regulation should facilitate, not frustrate, availability of low-volume pesticides. It is with this concern in mind that the forest industry comments on S. 2215 and S. 2346.

Comments on S. 2215

Conditional Registration

S. 2215 makes some helpful changes in the conditional registration process by which new uses are added to an existing pesticide registration. This process has been very important in extending the use of registered pesticides to smaller volume uses. While some of the changes are helpful, NFPA is concerned because Section 201 of the bill would make it more difficult for an applicant to gain access to a new use of an existing pesticide. Currently FIFRA allows an applicant for a new use of an existing pesticide to get a "conditional registration" by submitting "satisfactory data pertaining to the proposed additional use." The registration is called "conditional" because it is based on an existing use. The term "satisfactory data" is important because it allows the Administrator flexibility in imposing study requirements and timetables. S. 2215 changes the phrase in question to "all additional data," eliminating the Administrator's flexibility.

The flexibility in the current law--which is retained in S. 2346--allows registrants to put low-volume (low-profit) pesticides on the market without the initial burden of all the study costs. An appropriate (flexible) phase-in of requirements can mean the difference in whether a low-volume pesticide use remains (or ever becomes) available.

Reregistration

If there is one universally held opinion about FIFRA, it is that the reregistration process is too slow. However, some of the time periods set out in Title III of the bill would place unrealistic demands on EPA. The forest products industry is concerned with unreasonably short time periods because unrealistic time demands on the Agency have simply been ignored in the past. Reasonable time periods may be effective in speeding up the process; demanding the impossible will not achieve the goal.

Public Right to Know

Title V provides an effective way of collecting and distributing important information about pesticides through creation of "fact sheets". In addition, Title V should require that the pesticide label specify a source for the "fact sheet" so the pesticide user knows where to get the sheet and where to direct other interested people for information.

Interim Administrative Review and Cancellation Procedures

Under current law, pesticide registrants and users have a right to test in a cancellation hearing the validity of restrictions proposed by EPA staff on a particular pesticide use. This right is one of the major strengths of FIFRA. Cancellation hearing procedures allow those who have invested time and money in registering a pesticide, and those who depend on the pesticide to protect their crops, to have an independent assessment of the scientific and legal basis for restrictions proposed by EPA staff. While that process has occasionally been lengthy, it is, in the opinion of the forest products industry, without question the best method contained in any environmental law for assuring a proper scientifically sound decision on the merits.

The remedy for the perceived delay in reaching an ultimate Agency decision is not to tamper with the cancellation hearings instead, NFPA supports streamlining the interim administrative review process by setting time limits for the Agency to respond to comments. We disagree with any attempt to replace the adjudicatory cancellation hearing with a rulemaking. Section 702 would amend FIFRA Section 6(b)(1)(B) to allow an "informal rulemaking" instead of a cancellation hearing in some circumstances. NFPA does not object to the use of informal rulemaking to explore the need for "changes to the labeling of a pesticide" as proposed in Section 702. At the close of that process, however, the registrant or user should be afforded the opportunity for an impartial independent review of EPA's scientific and legal conclusions through a cancellation hearing.

NFPA supports the concept of shortening the cancellation hearing, but an arbitrary 12-month limit from initial notice to Administrator's decision will prove unworkable in many cases. An 18-month limit would still be tight, but would be workable in most cases.

A cancellation hearing following an interim administrative review (currently known as Special Review) performs the same functions as any other cancellation hearing. The NACA/CPR proposal to create a shortened cancellation hearing following a Special Review is unacceptable, not just because it imposes unreasonably short deadlines, but because it eliminates the fairness provided a pesticide registrant or user to present its own case fully and, most importantly, to test the EPA staff's case. NFPA agrees that a cancellation hearing following a Special Review, however, does not eliminate the need of those with an economic interest in the use of the pesticide to protect those interests in an independent forum. Proposed FIFRA Section 6(g) should be removed except for the provisions for introduction into evidence of the interim administrative review record.

Comments on S. 2346

As users of pesticides, members of the forest products industry would like to see a number of changes in FIFRA. To that end we support S. 2346. At this time, however, we will comment only on the three specific areas of most interest and concern to the forest products industry.

Federal Preemption of Local Pesticide Regulation Section 1903

As can be seen by the length and complexity of both S. 2215 and S. 2346, pesticide legislation and regulation is a highly complex and scientific undertaking. FIFRA provides for detailed regulation at the federal and state level. This is entirely adequate and FIFRA should explicitly preempt political subdivisions below the state level from regulating the use of pesticides on private property, as stated in Section 1903 of S. 2346.

Local jurisdictions are not equipped to make the highly sophisticated scientific analyses of risks and benefits which are necessary to make valid decisions about pesticide use. Nonetheless, there is a growing trend among counties and towns to impose regulations on the application of pesticides. It is inappropriate, indeed unfair, for a local jurisdiction to impair a citizen's ability to protect his crop, home, or lawn by regulating the use of a pesticide based on anything less than a thorough analysis of the risks and benefits. Local, politically-based regulation should not be allowed in an area, such as pesticide use, already subject to extensive federal and state control. Even if a political subdivision believes it has a localized problem, the state--not the locality--is better equipped to analyze the problem and design a solution.

Limitation on Pesticide User Liability Section 1003

All parties are interested in increasing compliance with the pesticide label by pesticide users. While some are exploring increasing state pesticide enforcement activities, pesticide users are interested in providing some incentive to obey the label. The pesticide label remains the foremost vehicle for informing and warning the pesticide user, and regulating the use of the pesticide.

NFPA suggests that efforts to improve label compliance emphasize both penalty and reward. NFPA supports Section 1003 of S. 2346 which limits the liability of those who obey the pesticide label.

Flexibility to Accommodate Low-volume Pesticide User Section 1704

EPA needs increased flexibility in regulating low-volume pesticide uses to help assure that important, beneficial uses are not inadvertently or unnecessarily removed from the market. Such flexibility is needed because, as discussed above, the burden of complying with a number of the regulations present a strong disincentive for pesticide registrants to maintain the smaller (less profitable) uses.

NFPA supports Section 1704 of S. 2346, which amends FIFRA to allow interested persons the opportunity to petition the Administrator to relax the impact of the Agency's regulations on low-volume non-food pesticide uses. The test for allowing or rejecting the pesticide use would remain the standard FIFRA test of whether or not the additional use would cause an unreasonable risk to man or the environment.

Conclusion

S. 2215 and S. 2346 provide the elements for a comprehensive bill to amend FIFRA. NFPA urges the Senate to pursue FIFRA amendments vigorously in 1986 and to consider the views of the forest industry in that process. We would welcome the opportunity to discuss these comments at the Committee's convenience.

STATEMENT OF EDGAR W. DUSKIN, EXECUTIVE VICE PRESIDENT, SOUTHERN AGRICULTURAL CHEMICALS ASSOCIATION, DAWSON, GEORGIA

The Southern Agricultural Chemicals Association appreciates the opportunity to present for the record its views concerning reauthorization and possible changes to FIFRA. We would have preferred presenting our views in person; however, we understand the tightness of the schedule for this hearing and request these remarks be made a part of the official record.

First, to place our association in proper perspective to the other groups testifying at the hearing, SACA is an independent regional association representing the interests of the agricultural pesticide formulators, distributors, and manufacturers who sell their products in thirteen southern states. We are based in Dawson, Georgia. The association was formed in 1954 in North Carolina, originally representing only the interests of formulators and distributors in Virginia and the Carolinas. Over the years the industry's interests have caused SACA to expand throughout the South. While we have some overlapping members and much commonality of interest with other trade associations who are presenting testimony, we speak primarily for those firms in the agricultural chemicals business who are independent regional or intrastate formulators, distributors, and dealers whose interests and viability also are critically affected by the actions you will take as a result of these and other hearings.

On balance, we could live with a simple two year reauthorization of the existing FIFRA. Major restructuring is not required; however, many fine tuning amendments which will facilitate its operation and clarify some gray areas would be extremely helpful. Adequate resources applied in the right places in EPA also are essential to proper functioning of FIFRA--changed or not.

We commend and generally support the NACA-Environmentalists Coalition attempts to resolve many long standing points of contention. Though not a direction part of the negotiations, we have been kept informed and have had the opportunity to comment and make suggestions. We can live with most of the legislation language proposed in S2215 and/or S2346. If FIFRA is to be changed we urge your consideration of our suggestions to better protect the interests of the "little people". This--without upsetting the spirit of the agreements reached and to cover areas of interest not covered in S2215. The following comments are keyed to the paragraphs of S2215. Following this are our suggestions to cover area of concern not addressed in the bill. Legislative language where appropriate can be provided for the record if desired.

-Concerning Title 3 - Reregistration and Revenues - For many years a major concern to us has been the slowness of the registration and reregistration process for "me too" and "new uses", as well as for new products. We hope that resources allocated in EPA's budget to product registration and reregistration both internally and by the Congress will be generously looked at. At the same time, we continue to oppose in principle the imposition substantial fees on applicants for registration of products. Though the basic manufacturers have agreed to one-time reregistration fees on active ingredients, an additional burden invariably trickles down disproportionately on the formulator-distributor who may have many end-use labels for many different formulations and mixtures of the same active ingredients. We urge that the levying of registration and reregistration fees on formulated products be specifically prohibited.

-Concerning Title 8 - False and Invalid Data - Our segment of the industry also supports stronger penalties against willful violators and falsifiers of data to include cancellation, fines, and jail. We emphasize the willful aspect. Non disruptive lab and other inspections should cause no problem. We are confident that in light of recent unfortunate happenings all labs and data are justifiably subject to much closer scrutiny and supervision both by ourselves as well as regulators. Public confidence in our product's effectiveness and safety is just as important to us as to those outside our industry.

We are concerned however, that the wording of this section of the bill could lead to the abrupt cancellation of a registration under circumstances of other than willful falsification. Under such circumstances we believe that in fairness a reasonable time should be allowed to replace questionable studies, to substitute ingredients, etc.

-Concerning Title 2 - Conditional Registration - We generally support the concept of this provision but caution once again that implementations as written can place a serious additional impediment to minor-use registrations since the administrator's discretionary authority is further limited. We are also concerned that the wording could also serve to negate the current limitation on the Administrator which prohibits him from using "lace of essentiality" as a criterion for denying registration.

-Concerning Titles 1 and 5 - Public Right-To-Know and Pre Access to Registration Data - We strongly support the provisions of both--so long as the access provided is used in good faith by all.

-Concerning Title 4 - Inert Ingredients - Freedom to freely substitute inert ingredients is of vital concern to formulators. While we recognize that additional data may be necessary to assure the safety of a small number, we hope that this provision will be used judiciously and not be used to require unwarranted and costly testing of a large number of products.

-Concerning Title 10 - Export - We support the concept and notification procedures. We hope that its inclusion will not cause jurisdictional claims among House and Senate Committees.

-Concerning Title 7 - Cancellation Procedures - While we sympathize with the need for expeditious review and decisions we oppose any procedure which would limit the registrant's right to question and refute the basis for EPA's actions and decisions and to know the source of all data relied upon in the decision. The language contained here minimally protects these rights but could be clarified and expanded. Though technically outside the context of this hearing we wish to record the fact that proposed budget cuts to USDA's Extension Service will affect its mission and ability to coordinate and develop "use" data through the Pesticide Impact Assessment Program. This could seriously affect a registrant's ability to refute EPA's allegations and to add to the "benefit" side of the risk-benefit equation.

-Concerning Title 12 - Employee Protection - We support the provision.

-Concerning Title 6 - Data Disclosure to States - We support the provision since we believe it would improve efficiency and reduce state requests for duplicate testing if EPA held test data could be shared with states when its laws concerning protection of data are equally as stringent as federal requirements.

Concerning Title 9 - Inspection of Laboratories - We expressed support of this provision when commenting of False and Invalid Data.

In addition we offered the following items concerning FIFRA which were not addressed in S2215.

-Concerning Preemption Below State Level - A potential problem of unrestrained and uncoordinated regulation continues to evolve as more and more localities attempt to severely restrict or ban use of certain pesticides. Except in extremely rare cases these actions are based on emotional reaction to fears generated by various sources. Localities lack expertise to critically and scientifically evaluate the problem. We believe regulatory actions should, at the lowest, be controlled at the state level where expertise is available. Preferably this authority should not be delegated; however, a system of state approval of local actions as in California could work in some states. Though a state now may take action to set the lowest level of regulatory authority, we believe it preferable to clarify the authority of states and intent of Congress in its choice of language in Section 24(a) and 24(c).

-Concerning Suggestions To Remove Indemnifications - We strongly oppose removal of requirements for EPA to indemnify owners and requirements to assume responsibility for disposal of pesticides when they are summarily suspended. This provision was placed in the law to protect small businessmen who through no fault of their own could be caught with a large portion of their assets in unsalable or unusable inventory with no recourse. We sympathize with EPA's problem of unbudgeted expenses, but do not believe this responsibility should be passed on to distributors and users. It would seem that a budgeted fund could be established in EPA to take care of such problems.

-Concerning the Right to Judicial Review of Arbitration Decisions - The right to judicial review of arbitration decisions under Section 3c should be afforded.

We believe compensation guidelines and principles should be established--preferrably by the concerned industry, but failing this by more arbitrary means. All parties involved in an "offer to pay" for registration data should have a reasonable concept of the basis on which the arbitrator will make his decision.

-Concerning Minor Uses - We believe that EPA should be required forthwith to establish separate simplified standards for low toxicity or low exposure products of the home and garden, horticultural, and sanitizer variety. Such would greatly facilitate speeding up the registration process since it would allow such products to be rapidly processed through the system, thus allowing more time and resources to be allocated to those posing greater risk. Incentives should be authorized for development of data supporting orphaned products for which there are existing minor use registrations or pending applications.

-Concerning Automatic Cancellation of Federal 24c Registration Upon Cancellation of the State Registration - Automatic cancellation of federal registrations for 24c state registrations when such are cancelled by the issuing state should be authorized.

-Concerning Suggestions to Eliminate Application of Restricted Use Pesticides By Persons "under the supervision of a certified applicator" - We understand the desire to improve safety in pesticide application through proposals to modify the provision which now authorizes restricted-use pesticides to be applied "under the supervision of a certified applicator". However, allowing restricted-use pesticides only to be applied by certified applicators could place impossible burdens on farmers and end-users. We believe that improved training of all applicators is the real key to improving safety in application. Efforts should be directed toward this instead of simply attempting to tighten rules on who may apply pesticides.

-Concerning Specific Authority For Use Of "end-use" Products In Formulations - On occasions formulators find it convenient to purchase small amounts of end-use material to complete a particular batch or mixture of the same product. The practice is long standing, in no way affects risk, and has been condoned by EPA. It is preferable that the law recognized the practice.

-Concerning NACA-CPR Agreement on "Groundwater" - We note a most recent general agreement concerning provisions in FIFRA for protection of groundwater from contamination by pesticides. We strongly believe that FIFRA is the most appropriate vehicle for such language and support the agreement.

This concludes our commentary. We hope that if future hearings are held, we shall be afforded the opportunity to present testimony in person.

STATEMENT OF JAMES B. GRANT, EXECUTIVE SECRETARY
NATIONAL ASSOCIATION OF STATE DEPARTMENTS OF AGRICULTURE

Mr. Chairman and Members of the Committee.

I thank you for the privilege of appearing before you on behalf of the National Association of State Departments of Agriculture (NASDA) and its affiliate, The Association of American Pesticide Control Officials (AAPCO).

Through the delegation of enforcement primacy under enforcement agreements between the Environmental Protection Agency and the state lead agencies, we have become the daily heartbeat of FIFRA in our respective states. From the initial hearings on FIFRA which resulted in the extensive amendments of 1972, and throughout the years since, we have worked with you, your Senate counterparts, the administration, commodity and user groups, environmental organizations and others in the development of current FIFRA, including the additional amendments of 1975 and 1978. We believe that the appropriate distribution of FIFRA's enforcement responsibilities between EPA and the state lead agencies has established a real partnership between this federal agency and the individual states. This partnership has resulted in an administrative and enforcement efficiency of complementing federal and state statutes which we feel is unsurpassed in any other joint federal-state program. We believe this delicate balance must be preserved, whatever the cost.

As with any regulatory program and especially one which addresses such technically complex issues as pesticides, their efficacy, and health and environmental impacts, it has become apparent that some additional statutory changes are necessary to keep FIFRA current with our vastly increasing knowledge, which continues to dictate changes in pesticide technology and safety considerations.

Over the last several years, a number of proposed changes have been considered by Congress, and even in recent months several organized groups have been devoting considerable efforts through negotiations to develop statutory language for amending FIFRA. While NASDA and AAPCO have not chosen to become a participating party to any of these group negotiations, we have been consulted by several of the groups, and have provided resource representatives to a few of their negotiating sessions, upon request. We are therefore aware of most of the major issues which are of concern to these various groups and which are being proposed for change.

A number of identified concerns involve the EPA programs per se, including registration and reregistration, conditional registration, tolerance setting and fees, labeling, registration fees, confidentiality, public right to know and access to data, and a number of other relevant issues. While most of these issues impact state programs in an indirect way, certain of these have the potential for serious impact upon the continuation of state pesticide programs. Registration and tolerance fees, for instance, will seriously affect the small formulator-registrant's ability to remain economically viable. Any losses of such registrants could seriously limit the local availability of pesticide products, adversely impact on local job availability and the local economy. Equally important is the fact that many states depend entirely upon registration fees to support their pesticide programs. Any loss of revenues from such fees could seriously impair pesticide programs in these states.

Other issues being considered for possible change far more dramatically impact upon state pesticide programs. Among these are applicator training and certification requirements, training and registration of uncertified applicators, dealer licensing, record keeping and reporting by both applicators and dealers, public access to records and worker protection. Our concerns relating to a number of these issues are of long standing, currently addressed on the basis of the recommendations made in late 1985 by the Environmental Protection Agency/States FIFRA Issues Research and Evaluation Group Certification and Training Task Force. EPA, through the Assistant Administrator for Pesticides and Toxic Substances, has committed to implementation of the recommendations of this Task Force and has specifically assigned personnel to demonstrate and support this commitment. The updating of state Plans for Certification of Pesticide Applicators is already underway and this effort alone will substantially upgrade the training and certification programs under FIFRA. Current efforts in the development of training resource documents and delivery systems in such specific areas as groundwater protection, endangered species, equipment calibration and other areas will appreciably strengthen the competency standards for pesticide applicators and ensure significantly greater protection to man and the environment. We feel that these efforts should preclude the need for statutory amendments to address a number of these issues which can be resolved administratively.

As your oversight hearings proceed, we would urge you to consider any proposed changes to FIFRA in terms of the following vital interests to the state lead agencies:

1. Preserving and maintaining the current balanced cooperative partnership between EPA and the state lead agencies in the administration and enforcement of FIFRA.
2. Accomplishing the FIFRA mandate of providing optimum protection to man and the environment, while avoiding the imposition of any unnecessary additional restrictions on pesticide registration and/or pesticide use which would result in the unavailability of an adequate supply of safe and effective pesticides to the user community for production of our food and fiber, and for adequate protection of our nation's health, and control of pests in our stored commodities and other products as well as our structural investments.
3. Ensuring that any expanded or additional requirements imposed upon or delegated to the states could be readily attained by the state lead agencies and that adequate funding would be provided to the states to accomplish the implementation of such requirements.

I want to sincerely thank you for the opportunity to present this brief statement of our concerns to this Committee. We are committed to cooperate with you in every way to achieve the best possible regulation of pesticides under FIFRA, and look forward to future opportunities for us to address in detail specific issues and changes in FIFRA which will be presented for your consideration.

STATEMENT OF WILLIAM C. BALEK
ASSOCIATION ATTORNEY
INTERNATIONAL SANITARY SUPPLY ASSOCIATION

Mr. Chairman and Members of the Senate Committee on Agriculture, Nutrition and Forestry:

The International Sanitary Supply Association (ISSA) has been in existence for over 63 years. ISSA is comprised of over 3,000 manufacturers and distributors of cleaning and maintenance products and supplies used in industrial and institutional settings such as hospitals, schools, food establishments, commercial businesses and other institutions. As such, ISSA is concerned with the vital role which sanitary maintenance plays in providing better public health for our nation. It was out of this concern that ISSA aligned itself with the FIFRA Coalition.

At the outset, we would like to emphasize that ISSA, as well as the FIFRA Coalition, shares the concern of the NACA-CPR group reflected in S.2215. We believe that pesticide legislation should ensure that such substances be safe and effective for their intended uses and that the manufacture and use of such substances not result in adverse effects on public health or the environment. It is in this spirit that ISSA appears before you today to present our problems and suggestions concerning S.2215. Additionally, ISSA would like to commend Senator Helms for introducing S.2346, which if adopted would contribute to a more effective regulatory performance by the Environmental Protection Agency.

REGISTRATION AND FEES - S.2215 levies a two part re-registration fee in an effort to speed up the registration process by hiring more EPA staff and to gain new financial resources to implement the program. ISSA also recognizes the need to speed up the registration process. However, the proposed fee schedule and re-registration process before the Senate would have a significant negative effect on the antimicrobial industry.

Two hundred eighty-six active ingredients account for only eight percent of antimicrobial production. Many of these active ingredients have an annual production of less than 10,000 pounds, generating sales of only $20,000 per year. Yet, S.2215 would impose a re-registration fee of as much as $150,000 per active ingredient. Additionally, the proposal would require all data gaps for these chemicals, no matter how insignificant, to be filled.

The EPA has estimated that between 62 percent and 85 percent of ALL active ingredients registered for antimicrobial use would drop out of the market if they were subjected to the above requirements. Approximately 200 ISSA members formulate disinfectants, sanitizers, fungicides, germicides and algicides under FIFRA as antimicrobial products. These members are supplied by basic manufacturers that register a total of 87 active ingredients, each with a slightly different molecular composition, different use and different EPA number.

Applying EPA's estimates, if S.2215 were enacted, 54 to 76 of the active ingredients purchased by ISSA formulators for antimicrobial use will no longer be available on the market. As a result, it is expected that a comparable number of antimicrobial end use products will also be dropped from the market.

The immediate repercussions of such a course of events will adversely affect the antimicrobial industry. But the impact will not stop there. The users of antimicrobials and the public at large will also suffer. Specialty sterilizers, germicides and disinfectants used to treat surgical instruments, medical devices, food processing equipment, drinking and processing water, etc., will no longer be available or available only at a prohibitively high cost. Such a situation itself would present a significant threat to public health which is certainly contrary to the intent of S.2215.

ISSA also opposes the fee system of S.2215 because it does not have an exemption for antimicrobials and therefore would result in producers of antimicrobials subsidizing the development of data for active ingredients other than their own beyond the original intent of FIFRA. The 1978 amendments to FIFRA provided for flexible data requirements for pesticide registration by directing EPA to make data requirements commensurate with the anticipated extent and pattern of use and degree of exposure of man and the environment to pesticides. S.2215 would remove this essential flexibility.

Antimicrobial products contain active ingredients which are low in toxicity and are biodegradable. The volume of these products sold is relatively small. Consequently, antimicrobials do not present a significant threat to the general public or to the environment as do agricultural pesticides. Additionally, because of their minimal toxicity, antimicrobial products are less likely to require any significant additional data. Nonetheless, S.2215 would require registrants of such products to pay as much as $150,000 for each active ingredient registered. This money would be deposited in a revolving fund and could then be used to fund the re-registration of other active ingredients. As a result, producers of antimicrobials in effect, would be subsidizing the development of data for active ingredients other than their own at a prohibitively high cost.

ISSA therefore opposes any assessment of re-registration fees that does not exempt antimicrobial products.

ANTIMICROBIALS - Senate Bill 2215, as well as current FIFRA law, regulates as pesticides such products as disinfectants, sanitizers, algicides, germicides and fungicides, in addition to agricultural and structural use pesticides. The former group of pesticides are antimicrobial products.

The confusion over the definition of "pesticide" in the federal law has led to enormous difficulties for the cleaning and maintenance industry. Many states, counties and municipalities are enacting or have enacted laws which regulate pesticides. These laws have inadvertantly regulated antimicrobials, resulting in overly stringent legislation regarding these products.

As a consequence, ISSA recommends that the federal law distinguish between antimicrobials and other pesticides. With this clarification in the federal law, states and other localities would not confuse these two groups and no longer accidentally impose unnecessary burdens on the use of antimicrobials.

INERTS - Although ISSA agrees that EPA should address those inerts which cause an antimicrobial to be a hazard to man or the environment, however, we disagree with the approach used in S.2215.

Senate Bill 2215 would require the EPA to publish a priority list of 50 inerts. An inert would be listed if it is in widespread use or results in widespread exposure. Any inert on the priority list must undergo a review by the EPA. In addition, such an inert must be identified by its most common name on the product's label.

This proposal, if adopted, would seriously affect producers of antimicrobials. In most situations, the identity and percentage composition of inert ingredients are closely guarded trade secrets. Indentification of inerts will increase the possibility that competitors will be able to reverse engineer the formula of any particular product.

Although ISSA agrees that there is a need to identify on the label those inerts that might present a hazard to man or the environment, we believe that such a treatment of inerts should be triggered only by evidence of adverse toxicity given the proprietary interests involved.

ISSA also believes that additional data should be generated for these inerts that may present a hazard, however, we believe that EPA already has sufficient authority under FIFRA Section 3(c)(2) to require the generation of any such studies. Consequently, there is no need to create a new elaborate data development plan for inerts. Furthermore, we suggest that the additional data collected under § 3(c)(2) be subjected to a risk assessment to be reviewed by the Scientific Advisory Panel.

In conclusion, ISSA and the FIFRA Coalition commend the NACA-CPR group for their fine efforts in producing S.2215. We hope to build upon, rather than tear down, what has already been constructed and hope our criticisms and suggestions are understood in this context. It is in this spirit that ISSA, as well as the FIFRA Coalition, seeks adoption of its bill, S.2346.

STATEMENT OF THE NATIONAL COTTON COUNCIL OF AMERICA
MEMPHIS, TENNESSEE

The National Cotton Council headquartered in Memphis, Tennessee, represents producers, ginners, seed crushers, warehousemen, merchants, cooperatives, and textile manufacturers from the Carolinas to California.

The cotton industry strongly supports a clean environment and safe use of chemicals. However, we are gravely concerned about the continued availability of essential pesticides that are currently registered and about the development and registration of new pesticides that are safer, more effective and less expensive.

We recognize the need for, and support, reasonable regulations for pesticides. However, we are concerned about imposition of unnecessary rules that would make many essential pesticides unavailable to farmers even though they are registered and in the marketplace.

At the Council's 1986 Annual Meeting, delegates representing all seven segments of the U.S. cotton industry unanimously adopted the following resolution on pesticides:

> Continue supporting legislation and other measures to facilitate sound development and use of essential agricultural chemicals, and, in particular:
>
> - Urge expeditious clearance of needed new cotton pesticides; continued registration of older pesticides unless there is scientific proof that their use presents an imminent hazard or that the risks outweigh the benefits; and seek ways to assure continued availability of non-proprietary pesticides under the data call-in and reregistration process;
> - Support new negotiated rules that exempt states from provisions of FIFRA under emergency situations;
> - Urge that buffer zones, minimum dilutions, and other pesticide application restrictions be imposed only upon valid, scientific proof that they are necessary to prevent a physical health hazard to humans or animals;
> - Continue to support federal and state preemption for overall pesticide regulatory authority and federal preemption for setting residue tolerances; and support continued use of residue action levels where appropriate in absence of tolerances; and
> - Continue to encourage appropriate use of cottonseed oil as a pesticide carrier and in pesticide formulations; assess research needs and encourage studies so that maximum benefits of this technology can be realized; support federal and state regulatory actions and data requirements that do not restrict registrations and use of pesticides with cottonseed oil unless there is scientific proof that there are increased hazards which outweigh increased benefits; and urge regulatory agencies, in determining the need for such requirements and restrictions, to consider

the safety record of previous use on an individual crop basis.

We have some very strong concerns that need to be addressed by amending the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Before taking our positions on these, we recognized and took into consideration three fundamentals.

First, changes made in the law should not deny or unjustifiably restrict the use of pesticides by farmers and/or increase their production costs.

Members of this Committee are very familiar with the economic situation on U.S. farms. You read and hear about the large number of farms "going under". We believe that you don't want to pass legislation that would add to the already heavy economic burden for U.S. farmers.

Second, amendments to FIFRA should not increase the resource burden to the U.S. Environmental Protection Agency (EPA) or the state agencies responsible for administering the law.

We support the overall thrust to move toward a balanced budget. One of the easiest and most "palatable" approaches is to eliminate, and certainly not add any new, unnecessary regulatory legislation, the costs of which outweigh the potential benefits.

Third, the environment should be protected to no less degree than the current FIFRA provisions provide.

As stated earlier, we strongly support a clean environment and safe use of agricultural chemicals.

Our staff has reviewed the proposed FIFRA legislation (S.2215) developed by the National Agricultural Chemicals Association (NACA) and the Campaign for Pesticide Reform (CPR) -- a coalition of national environmental, labor and consumer organizations.

It is encouraging to those of us in agriculture to see groups with such diverse past differences with regard to pesticide legislation and regulation work together in developing proposed legislative changes in FIFRA. However, an important segment, agricultural users, played no role in developing the amendments proposed by NACA and CPR which have been introduced as S.2215, the "Federal Insecticide, Fungicide and Rodenticide Act Amendments of 1986."

Some of the changes that S.2215 would bring about go against at least one of the three fundamentals that we earlier stated should be met. For example, the proposed reregistration fees would add to the already heavy economic burden for farmers; and some of the timetables, such as that for reregistration, will increase the resource burden for EPA and state regulatory agencies.

Provisions of the "Pesticide Reform Act of 1986" (S.2346) on most, if not all, of the issues covered in that bill are more in keeping with the interests of the National Cotton Council. However, there are some issues of importance to the Council that are not addressed in either S.2215 or S.2346.

Specific concerns of the Council are discussed in greater detail in the sections that follow. Where deemed appropriate, the relationships of our concerns to the provisions of S.2215 and S.2346 are noted.

Federal and State Preemption for Overall FIFRA Authority -- When the major overhaul of FIFRA was made with the 1972 amendments, Congress granted limited authority for states to regulate pesticides. Legislative history indicates the Congress intended to share Federal authority with the States, but not with local jurisdictions. Yet, there have been numerous incidents where city and county governments have embarked on efforts to regulate pesticides at the local level.

Both the National Association of State Departments of Agriculture and the Association of American Pesticide Control Officials have endorsed Federal and State preemption to regulate pesticides.

Having different local regulations is unnecessary and will create unworkable situations and undue hardships for farmers and other users. The National Cotton Council strongly endorses amendments making it clear that FIFRA does not extend pesticide regulatory authority to local jurisdictions beyond the state level.

S.2215 does not address this issue. On the other hand, S.2346 does and its provisions agree with the National Cotton Council's position.

Federal Preemption for Setting Pesticide Tolerances -- Agricultural commodities and products made from agricultural commodities must be allowed to move across state lines without any unnecessary restrictions. It is completely unworkable and unnecessary for states to set pesticide residue tolerances. In addition to being costly, it would create mass confusion where the same commodity had different tolerances for the same pesticide in different states. States don't need and should not have the authority to adopt the same tolerances set by EPA because that could result in increased program costs for the states.

We strongly support amending FIFRA to provide for Federal preemption in this area.

S.2346 generally agrees with the Council's position while S.2215 doesn't address the issue.

Tolerances For Imported Agricultural Commodities -- The Cotton Council strongly favors FIFRA language requiring all imported agricultural commodities and their processed products to meet U.S. tolerance standards for pesticide residues. Allowing pesticide residues in excess of U.S. standards is totally unfair to U.S. growers who must bear the cost of meeting the standards.

This issue is not addressed in either S.2215 or S.2346.

Fees For Registering and Reregistering Pesticides -- In the past few years, there has been a movement underway to shift costs from the government and taxpayers-at-large to specific groups that are the principal users of the services or materials. As the movement continues, anyone who requests information will be required to pay the cost of collecting and distributing information.

EPA has been charging rather large fees for setting pesticide residue tolerances. Recently these fees were increased substantially. In a sense, the tolerance fees are "registration" fees since most pesticides must have tolerances established in order to be registered.

There are two Federal statutes that require pre-clearance of specific products before they can be manufactured, sold and used. One is FIFRA and the other is the Federal Food, Drug, and Cosmetic Act (FFDCA). In each case, pre-clearance and registration of products broadly benefit the general public.

Congress has consistently rejected registration fees for drugs. This should set a precedent for rejecting registration and reregistration fees for pesticides. Pesticides should not be singled out for special user or registration fees when other products such as drugs under pre-clearance statutes are specifically exempted from such fees.

Such fees would:

- Result in higher pesticide costs that would be passed on to farmers and ranchers who, historically, have not been able to pass on such costs to consumers of farm and ranch commodities;

- Tend to restrict innovative research and development especially of (1) products for use on minor crops and minor uses on major crops and (2) products that may be safer and more environmentally sound yet not any more biologically effective in controlling target pests.

  For minor uses (uses with low market potential), imposition of registration fees could actually be a major factor in a company's decision not to pursue registration;

- Have a disproportionate and unfair adverse impact on small businesses.

  Reregistration fees as proposed in the S.2215 suggested amendments, in particular, will adversely impact numerous small registrants of non-proprietary products. This relates to another serious problem or concern we have about the loss of many useful older pesticide products in connection with EPA's data-call-in and reregistration programs even without the imposition of reregistration fees. This is discussed as a separate item later;

- If used to pay most of EPA's expenses, the fees would remove most cost constraints on the Agency regulatory operations. Also, it would leave little incentive for Congress to scrutinize EPA's programs to see if they are necessary and/or cost-effective; and

- It will be virtually impossible, particularly with flat fees, to distribute the costs equitably among registrants and users.

The provisions of S.2215 will impose reregistration fees for active ingredients. As stated earlier, the Council's position is against fees for registration and reregistration. S.2346 doesn't address such fees.

Use of Restricted-Use Pesticides Under Direct Supervision of a Certified Applicator -- With the 1972 FIFRA amendments, Congress wisely provided that restricted-use pesticides may be applied by a certified applicator or by a person under the direct supervision of a certified applicator. Over the last 2-3 years, EPA and several environmental, labor and consumer groups have suggested amending FIFRA to eliminate the provision that allows restricted-use pesticides to be used "under the direct supervision" of a certified applicator. The justification given is that under the present statutory language, the Agency's ability to limit use to competent applicators can (emphasis added) be easily thwarted. The truth is no one has presented any factual evidence to show that there have been problems during the past 13 years under the present statutory language.

We contend that removing the phrase "under the direct supervision of a certified applicator" will create hardships on farmers whether or not it is the farmer himself or someone else such as a private agricultural consultant hired by the farmer who is the certified applicator that supervises the use. Therefore, the National Cotton Council endorses the present FIFRA language on this subject.

S.2215 does not address this issue. Under Title XIII - Certification, Training and Recordkeeping Amendments in S.2346 this issue is addressed for commercial applicators. For private applicators, the provisions of S.2346 don't specifically mention this issue. S.2346 does call for training and retraining of both certified and non-certified private applicators. However, it makes no distinction between certified and non-certified applicators as to the level of training. Requiring the same level of training for certified and non-certified private applicators in effect changes the present provision of FIFRA on this issue and the Council is opposed to such change.

Lack of Essentiality Should Not Be A Criteria Against Registration of Pesticides -- In 1972, Congress, in its wisdom, provided under Section 3 of FIFRA that "EPA shall not make any lack of essentiality a criterion for denying registration of any pesticide" (emphasis added). That is, just because a pesticide is already registered for the same use, another pesticide should not be be denied registration for that use.

Congressional intent is being thwarted by EPA contending that the "lack of essentiality" provision in the law does not apply to conditional registrations. Practically all new products are being given conditional rather than full registration.

We believe that Congress' intent was that EPA also should not use lack of essentiality as a criterion for cancelling pesticides, yet the Agency continues to do so in connection with Special Reviews (formerly known as Rebuttable Presumption Against Registration or RPAR).

This issue is not addressed in S.2215. Provisions of S.2346 are consistent with the National Cotton Council's position.

Guidelines for Registering Pesticides -- EPA has made considerable progress in developing guidelines to inform potential pesticide registrants what the various registration requirements are. Yet, we continue to hear of numerous incidents of chemical companies conducting all the tests and obtaining the data called for in the guidelines, and the Agency delaying registration by adding additional requirements not covered in the guidelines. In a few cases, it seems that EPA doesn't know what it wants. A specific example is the case of aquatic or pond studies for registration of synthetic pyrethroids.

The Agency doesn't seem to know, or at least won't tell the potential registrant, what type of pond study will be satisfactory.

Addressing this problem through amendments to the statute is probably not appropriate so we suggest that it be handled in the legislative report that accompanies amendments passed by this Congress.

The provisions on registration guidelines in S.2346 are satisfactory. This issue is not addressed in S.2215.

EPA vs. OSHA Jurisdiction -- FIFRA preempts pesticide exposure standards and regulations to EPA. Some anti-pesticide groups have advocated transfer of jurisdiction regarding pesticides in farm workplaces from EPA to OSHA.

In the early 1970's, a jurisdictional squabble between EPA and OSHA arose with regard to pesticide-treated field reentry standards. The Cotton Council and other farm groups endorsed the obvious statutory authority of EPA. We thought this issue was settled. However, in the last year or so, EPA suggested that FIFRA could be amended so that EPA actions do not preempt OSHA provided that OSHA's actions are not inconsistent. Some labor and environmental groups support at least joint OSHA-EPA authority.

We strongly endorse authority over the farm use of pesticides under FIFRA remaining in EPA rather than being shared with OSHA. Even if the actions by both agencies are consistent, the result will be additional unneeded regulatory burdens on farmers and increased overall Federal costs without upgrading the safety level of farmers and farmworkers.

Neither S.2346 or S.2215 addresses the issue of EPA vs. OSHA jurisdiction.

Use of a Registered Pesticide at Less Than Label Dosage, Concentration or Frequency, or against a Target Pest Not On The Label -- Section 2(ee) of FIFRA provides among other things that:

> "The term 'to use any registered pesticide in a manner inconsistent with its labeling' means to use any registered pesticide in a manner not permitted by the labeling: provided, that the term shall not include (1) applying a pesticide at any dosage, concentration, or frequency less than that specified on the labeling, (2) applying a pesticide against any target pest not specified on the labeling if the application is to the crop, animal, or site specified on the labeling, unless the Administrator has required that the labeling specifically state that the pesticide may be used only for the pests specified on the labeling after the Administrator has determined that the use of the pesticide against other pests would cause an unreasonable adverse effect on the environment...."

We know that some groups have proposed changing this language so that if the label specified that "use at less than label dosage (etc.) is prohibited" then it would be a misuse for a farmer to apply a registered product at less than label dosage, etc.

The Cotton Council strongly endorses leaving the language of Section 2(ee) as it is. Some farmers who are good managers are able to use pesticides at lower rates and/or less frequently than specified on labels without sacrificing pest control. Such practices are economically beneficial to the farmer and are environmentally sound. We think the proposed change mentioned above would lead to most labels having statements prohibiting use of lower dosages, etc., because registrants are in the business to sell as much of their products as possible.

S.2346 amends the language of the present law, but the change won't create any problems for the cotton industry. This issue is not addressed in S.2215.

Conditional Registration of Pesticides -- Under the current provisions of FIFRA, new pesticide products can be "condition- ally" registered if most but not all of the data requirements have been met. Under such registrations, the registrants must commit to generating and submitting the additional data required and provide interim reports to EPA on the progress of the required studies.

Conditional registrations are granted for specified periods. The Agency can, and sometime does, extend the period of a conditional registration when additional time is needed to complete the studies.

Some groups advocate doing away with EPA's legislative authority to register new pesticides conditionally. EPA's authority to conditionally register new pesticides has been extremely helpful to agriculture. Without such authority, we probably would not have available for use today the very important synthetic pyrethroid insecticides. The major problem has been that the Agency wanted pond or aquatic studies on invertebrates and vertebrates, but it was undecided what research protocols would be satisfactory.

The National Cotton Council strongly endorses leaving the current FIFRA language on conditional registration as it is.

The provisions of both S.2215 and S.2346 would allow conditional registration of additional or new uses of pesticides. However, restrictions under both bills would probably eliminate new active ingredients from being conditionally registered.

Inert Ingredients -- The term "inert ingredient" is defined in FIFRA as an ingredient which is not active. We agree with most scientists and others who believe that some inerts have some activity. In addition to the chemical nature of the inert itself, activity of inerts may be influenced by several factors including the active ingredient with which it is used, the formulation of the pesticide product, and the conditions (temperature, etc.) under which the product is used.

Several groups including EPA have expressed varying degrees of risk concerns about inert ingredients. The proposed S.2215 amendments would add a new Section 3(h) to deal with inerts. It would require EPA to establish and publish an initial priority list of 50 inert ingredients that the Agency has reason to be concerned about. The list would be subject to change but could never drop below 50 or consist of more than 75 inert ingredients at one time. These proposed amendments specify a timetable to (1) determine what additional data the Agency needs, (2) propose and finalize a Data Development Plan, (3) comment on the proposed plan.

The National Cotton Council supports new FIFRA language that provides EPA a broad but flexible authority to focus on those inerts for which there are valid reasons to believe they pose a significant risk to health or the environment. Through publication in the Federal Register and by other means, users and other groups as well as registrants should be made aware of the inerts that the Agency focuses on. We do not think it is necessary, scientifically logical, or practical for the law to specify how many or how few inert ingredients must be on a priority list.

We believe the amendment language proposed by S.2215 to deal with inerts would place severe and unnecessary dollar and manpower burdens on EPA. We are also concerned about the impact it will have on delaying registration of new pesticides and reregistration of older pesticides. Of particular concern is the impact on pesticides for minor uses. The language on inerts in S.2346 is more acceptable.

The language for Sec. 405(i) "Substitution of Inert Ingredients" is identical in the two bills and is not very clear. In fact, we think it reads, in part, the opposite of what was intended. As it currently reads, the Administrator would approve substitution of an inert ingredient if the substitute inert was similar in molecular structure to a chemical known to cause significant adverse effects. We suggest that the language of this Section be changed by including the word "not" as shown below:

> SEC. 405. SUBSTITUTION OF INERT INGREDIENTS.
>
> Section 3(7 U.S.C. 136a) (as amended by section 404 of this Act) is amended by adding at the end thereof the following new subsection:
>
> "(i) SUBSTITUTION OF INERT INGREDIENTS. -- The Administrator shall approve an application to amend the registration of a pesticide to substitute an inert ingredient for an inert ingredient listed under subsection (h)(1), if the Administrator finds, on the basis of similarity in molecular structure to a chemical known not to cause significant adverse effects, existing data, or such short-term tests as the Administrator determines are necessary, that the substitute inert ingredient does not pose the same or similar concerns about unreasonable adverse effects on the environment that resulted in the listing of the listed inert ingredient.".

Pesticide Residue Action Levels -- A decision by the U.S. Circuit Court of Appeals for the District of Columbia within the past two years raises doubt about EPA's authority to set pesticide residue action levels. The Court said that the Federal Drug Administration (FDA) had no authority to set action levels for aflatoxin, a naturally occurring toxin, in corn and other commodities. It further said that FDA is statutorily required to establish tolerances through the formal process.

We feel strongly that both FDA and EPA need authority to set action levels. There are several situations where pesticide tolerances are not appropriate and where EPA has set needed action levels.

The National Cotton Council favors amending FIFRA to make it clear that EPA has the statutory authority to set pesticide action levels when they are more appropriate than tolerances.

Neither S.2346 or S.2215 addresses the issue of pesticide action levels.

Private Right of Action -- Amending FIFRA to include a "private right-of-action" provision would create a Pandora's box. It would allow any person who felt aggrieved by supposed misuse of a pesticide to bring suit against farmers and ranchers. Instead of enhancing protection under FIFRA, such a provision would encourage law suits. The current remedies under FIFRA and other statutes are adequate.

Congress has considered similar proposals before and had the wisdom to reject them. The Cotton Council urges that such provisions continue to be rejected.

Private right-of-action is not addressed in either S.2215 or S.2346.

Public Standing to Initiate Cancellation Hearings, Etc. -- We also strongly oppose any new provisions in FIFRA to give the public standing to initiate suspension or cancellation hearings. Our reasons are similar to those we have stated for our opposition to private right-of-action provisions.

This issue is not addressed in S.2346 or S.2215.

Special Reviews, Adjudicatory Hearings and Cancellation Procedures -- EPA has let it be known that it would like for FIFRA to be amended to eliminate adjudicatory hearings and to convert the current public notice and comment period into informal rulemaking.

Under both S.2215 and S.2346, significant changes are made in Section 3(c)(8) of FIFRA that deals with Interim Administrative Review of pesticides. The proposed language establishes a "risk-only" trigger for initiating such a review based on "levels of risk" and allows the review to proceed even in the absence of exposure data. Since nearly all products have some level of risk, it is impossible to work with a "zero-risk" concept.

We feel strongly that the law should provide for a balanced assessment taking into account risk and benefit levels. Also, we think the 30-day period allowed in the S.2215 amendment is much too short for responding to a notice. It should be remembered that the Administrator of EPA now has, and will continue to have authority under Section 6(c)(3) of FIFRA immediately to suspend registration of a pesticide to prevent an imminent hazard to human health.

We agree that cancellation proceedings are often too long and drawn out and that the procedures need to be streamlined. However, because of the serious consequences to farmers and ranchers of the outcome, we favor retaining the current 2-stage process -- (1) public notice and comment and (2) adjudicatory process.

Indemnification and Disposal -- When EPA suspends and later cancels registration of a pesticide, the Agency is required by law to indemnify owners of existing stocks and to pay for disposal of those stocks.

We support keeping such statutory requirements. The indemnification provision serves as a cost constraint on any precipitous cancellation of pesticide based on inadequate information. Farmers and ranchers who have existing stocks on hand, however, should have the option of using them for labeled uses unless it can be shown that health or environmental risks through such use would be too great.

S.2346 authorizes funding a revolving fund to carry out indemnification provisions of FIFRA. The issue is not addressed in S.2215.

Pesticide Standards to Protect Workers and Others -- We are strongly in favor of adequate workable standards which promote safe pesticide application and use. We oppose careless and irresponsible application and use that could endanger the health and property of persons in and around pesticide treated fields.

Dr. Jim Brown on our Technical Services staff represents the Cotton Council on an EPA advisory committee that is currently developing new farmworker protection standards for agricultural pesticides.

EPA has plenty of authority under the present FIFRA language to promulgate adequate regulations to protect farmworkers and others. There is no need for amendment to the statute in regard to buffer zones, notification requirements, etc.

Public Right-to-Know -- S.2215 would require that pesticide registrants prepare and submit to EPA "Fact Sheets" which contain the name of the pesticide active ingredient and inerts that are of concern plus a summary of relevant health, safety and environmental data. It requires both the Agency and registrants to make these fact sheets available to the public upon request.

S.2346 provides for "Material Safety Data Sheets" similar in form and content to Fact Sheets.

The cotton industry fully supports the idea of sharing health, safety and environmental data with the public. Farmers, like other segments of the public, want this information also.

We are not sure if this issue of public right-to-know should be covered in the statute or in committee report language. We feel, however, that the system for gathering and distributing the information should be as simple and inexpensive as possible. It is suggested also that states have a role in distributing the information.

Risk and Benefit Assessments in General: Who Should Make Them? -- We think that almost everyone agrees that EPA should be the primary party for making risk assessments of pesticides. Congress wisely charged the Agency with this responsibility. Most people also feel that registrants and others should have the right-of-rebuttal to the risk assessment. We strongly support this right.

When it comes to benefits assessment, we feel that EPA is not as well qualified to make such assessments. This concern has been magnified by what we have seen taking place the last few years.

The U.S. Department of Agriculture and state agricultural institutions are better staffed to make benefit assessments of agricultural pesticides. In the last few years, EPA has been using these agencies less and less. Instead, it is depending more and more on its own staff to gather the information and make the assessments.

We can only assume that the Agency has had to expand its staff of agricultural economists, agronomists, entomologists, plant pathologists, weed scientists, engineers, etc., in order to carry this out in-house.

Even with an expanded staff, EPA does not, and probably cannot, do as good a job on benefit assessments as can be done by USDA and the state universities. Within the past six months, EPA management requested Cotton Council technical staff to review a draft benefits assessment document developed within the Agency on an important cotton pesticide being considered for Special Review. The request came about because the internal draft document showed minimal benefits from use of the particular pesticide yet management was picking up information from farmers in various parts of the Cotton Belt about how important and beneficial it was.

As far as we know, EPA has yet to ask USDA and the states to assess the benefits of using this pesticide on cotton.

In the late 1970's, when EPA initiated its rebuttable presumption against registration or RPAR program (now called Special Review), a National Agricultural Pesticide Impact Assessment Program (NAPIAP) was started in USDA. Each year since, Congress has appropriated a sizeable sum of money earmarked for NAPIAP. Some of this money is used by USDA and some of it goes to the states. There is obvious duplication of staff and effort if EPA does not use this highly qualified group of scientists, but instead maintains its own separate staff.

We suggest that FIFRA be amended to provide that USDA in cooperation with the states has the primary responsibility to prepare pesticide benefit assessments and direct EPA formally to request such assessments when one is needed for a particular pesticide or class of pesticides in connection with Interim Administrative Reviews, Special Reviews or Cancellation Proceedings.

EPA should have the right-of-rebuttal in regard to the benefit assessments. Of course, this means that the Agency must have a small well-trained cadre of technical people -- economist, entomologist, agronomist, etc. It should not take nearly as large a staff, however, as is required if EPA has the primary responsibility for making the assessments.

This issue is not covered in either S.2346 or S.2215.

Employee and Employer Protection -- The S.2215 amendments would add a new Section 32 to FIFRA. It would require that no employer may discharge or otherwise discriminate against any employee with respect to the employee's compensation and conditions of employment because the employee, or a person acting at the request of the employee, has initiated a proceeding under FIFRA, testified, or otherwise participated in such a proceeding or in any other action to carry out the purposes of the Act.

The National Cotton Council feels that this amendment is unnecessary. If it is to be enacted, then we strongly support its expansion to provide protection to farmers and other employers from intentional vengeful or malicious actions by employees.

S.2346 does not address this issue.

Rereview and Data-Call-In -- One of our biggest immediate concerns is the threat of losing numerous older pesticide products that are still valuable in cotton production.

Under its reregistration program, EPA, as it should, is reviewing its data files on older registered products. Then the Agency proceeds with data-call-in by notifying registrants as to what additional data they must generate and submit in order for the data files to be brought up-to-date with the registration requirements under which new pesticides have been registered. In most cases, this means large financial and manpower commitments by the registrants over a period of 2-3 years to conduct the studies necessary to generate the additional data. If a registrant fails to supply, or show intent to supply by developing appropriate protocols and initiating required studies, EPA suspends registration of the product.

The seriousness of the problem arises from the fact that patents have expired on many of these older products and many of the registrants are small businesses. Not having proprietary rights, these registrants are, understandably, reluctant to spend huge sums of money to save such products without having any market protection. Even if they make the commitment, it might be for naught if the data generated doesn't satisfy EPA.

Notices of intent to suspend under this program have already been issued for several important older cotton pesticides.

Mr. Chairman and members of this Committee, we are seeking help and advice on how to minimize the impact of this on agriculture.

In closing, we want to express appreciation for the opportunity to provide our views on FIFRA legislation and related regulatory matters to the Committee.

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STATEMENT OF JOHN F. HALL, PRESIDENT
AMERICAN WOOD PRESERVERS INSTITUTE

The American Wood Preservers Institute (AWPI) appreciates this opportuntity to comment on the reauthorization of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

AWPI is a national trade association representing the wood preserving industry, which is comprised of both producers and users of wood preserving pesticides. AWPI's membership includes twenty-six manufacturers, formulators, and importers of wood preserving pesticides and fifty-nine wood treating companies. Wood treating companies are the primary users of wood preserving pesticides. AWPI's treater members have approximately sixty percent of the nation's wood treatment capacity.

Although wood preservatives are large volume pesticides, they are produced by a variety of companies, many of which are small in size. These companies and their products compete against each other in the marketplace. Because of this competition, profit margins are small. This competitive situation also makes it difficult for producers to spend large sums of money on reregistering and filling data gaps for the wood preserving pesticides. In addition, narrow profit margins and the competitive nature of the industry also limits expenditures on research for new or alternative wood preserving pesticides.

AWPI supports enactment of a multi-year reauthorization of FIFRA. Changes are needed in FIFRA, and AWPI has participated in efforts to resolve differences between interested parties. We believe that it is important to join with other interested parties to reach the goal of a a multi-year FIFRA reauthorization.

We commend the National Agricultural Chemicals Association (NACA) and the Campaign for Pesticide Reform (CPR) for the contributions they have made that have resulted in the introduction of S.2215. However, AWPI believes that S. 2346, the Pesticide Reform Act of 1986, is a better approach to the subject -- especially in the areas of reregistration of pesticides, conditional registration, inert ingredients, and certification and training. S. 2346 represents the efforts of over 40 pesticide user groups and meets the goal of assuring safe and effective pesticides while maintaining the nation's economic health.

Several sections of the prepared legislation affect the wood preserving industry most directly. These are: (1) Reregistration Fees, (2) Inert Ingredients, (3) Cancellation Procedures, and (4) Certification and Training.

Reregistration Fees

AWPI supports the provisions in S. 2346 that address reregistration of existing pesticides. S. 2346 does not require payment of registration fees as would be required by S. 2215. In order to reregister a pesticide under S. 2215, a registrant will be charged fees totaling between $100,000 and $150,000.

While we agree with the intent of S. 2215's section on reregistration, i.e., to expedite reregistration of existing pesticides and provide the government with resources to do so, we object to the imposition of reregistration fees on registrants. EPA resources to accomplish this goal should not come from registrants. Registrants will bear an enormous burden in fulfilling outstanding data requirements identified during the reregistration process. Additional burdens on wood preservative registrants will be another disincentive to the reregistration of these pesticides with low profit margins.

AWPI also views S. 2215's system of reregistration fees as a mechanism which taxes a few to finance a regulatory system that benefits many. When government services benefit society generally, the expense of those services should be borne by the taxpayers at large, not by individuals. All of society will benefit from reregistration procedures that result in safe and effective pesticides. Therefore, AWPI suggests that Congress increase EPA staffing through an additional or increased appropriation to achieve this goal.

There are other reasons why AWPI opposes the adoption of reregistration fees and S. 2215's fee implementation mechanism. (1) Product development costs would be increased dramatically if a system of pesticide reregistration fees was implemented. (2) A flat, indiscriminate reregistration fee fails to distinguish between agricultural products that have a high potential for human contact, and non-agricultural products with less potential for human contact. (3) The fee in S. 2215 is not based on the actual time it takes EPA staff to register the product. (4) S. 2215 has no exemptions for minor use products, including those for both agricultural and non-agricultural uses.

On this issue, we would like to restate that one of the major reasons that AWPI is supporting S. 2346 is that it contains no proposal for reregistration fees.

Inert Ingredients

Inert ingredients have been the focus of great deal of interest by the Environmental Protection Agency and various user, producer and environmental groups. We commend EPA's efforts in this area, including the Agency's identification of 55 inerts of immediate toxicological concern and its creation of a comprehensive policy strategy, to evaluate and regulate inerts.

The mechanism in S. 2215 for the testing of inerts is unwieldy. We agree with the National Audubon Society that the establishment of a rotating priority list and its rotations are very cumbersome. S. 2215 provides for an initial list of 50 inerts, with 25 more to be added. The list would have a floor of 50 inerts which would make it dynamic, i.e., a replacement must be made for every inert coming off the list. This dynamic list could establish a system by which the Agency could review and require testing on more than one thousand inerts over the next decade. This minimum floor of 50 inerts would force the Agency to review inerts that the Administrator might not have chosen to examine, because they do not pose a risk to man or the environment. Examples of inerts that do not pose such a risk are cookie crumbs used in rat poisonings, or water which is added to many chemicals.

The establishment of a dynamic inert list is resource intensive and could result in the diversion of agency resources away from the assessment, evaluation and control of significant health and environmental risks.

S. 2215 would force the Administrator to indiscriminately consider all types of inert ingredients, whether they are deliberately added to the pesticide by the registrant or are incidental contaminants that are formed during the production process. At a minimum, incidental contaminants that are formed during the production process and that are inextricably linked to the technical grade product should be exempted from this provision, because data generated to support the registration of the product most likely will be based on tests conducted with the technical grade product. Therefore, test results on the technical grade product should demonstrate any potential cumulative health or environmental effects attributable to the product and its incidental contaminants.

The Agency has asked for only 3 legislative changes on inerts: (1) clarification of its authority to list certain inerts on product labels, (2) authority to require data necessary to evaluate inerts, and (3) a mechanism to limit the size of the list of inerts. AWPI believes that a simple mechanism to give this requested authority would be a better solution than the elaborate system that S. 2215 would put into place.

Cancellation Procedures

AWPI is extremely sensitive to the implications of any changes in cancellation procedures because of its recent experience in a nine-year Special Review (formerly RPAR). We agree that this process must be shortened and improved. However, the provisions in S. 2215 foster new controversies, including the risk-only trigger, the shift to informal rulemaking and the mandatory time limits.

S. 2215 contains a risk-only trigger which is burdensome as it is extremely difficult to work with a zero risk concept. S. 2346 contains criteria developed by EPA which AWPI believes to be superior to a zero risk trigger. This criteria is based ona rule that the Agency published in the Federal Register on November 27, 1985, containing a detailed criteria for a Special Review.

S. 2215 would add a new "informal rulemaking" as an alternative to a cancellation hearing. AWPI does not believe that this alternative would be fair to users or registrants. This "informal rulemaking" would allow EPA to impose restrictions on a pesticide which neither the registrants nor the users could dispute in a cancellation hearing. AWPI, in light of its recent experience with special review and cancellation procedures, does not believe registrants and users should be denied the recourse of a cancellation hearing.

The right to a cancellation hearing following a special review is an important procedural right for registrants and one of the major strengths of FIFRA. This right helps to ensure that EPA's factual basis for a decision is sound and its decision is prudent and reasonable. In many cases it is appropriate or necessary to have an impartial third party decide whether these matters have been resolved appropriately.

AWPI supports of a shortened time period for a cancellation hearing. However, the arbitrary 12-month limit from initial notice to Administrator decision contained in S. 2215 is unworkable. AWPI supports the more reasonable 18-month time limit contained in S. 2346.

Certification and Training

S. 2215 contains no section on Certification and Training. However, S. 2346 has an extensive section dealing with this area. AWPI supports changes represented by the Certification and Training Sections of S. 2346.

Section 101 of Title I and title III of S. 2346 (as well as Section 101 of title I of the bill) provide expanded and updated training requirements for certified applicators as well as for non-certified applicators who work under supervision of certified applicators. There are also mechanisms for the verification of the training of these types of applicators by the state lead agency. Therefore, S. 2346 would strengthen the requirements of existing law.

The certification and training sections in S. 2346 are necessary for the safe application of pesticides. AWPI therefore urges the Committee to adopt these sections.

AWPI views the certification and training requirements of S. 2346 to be extremely thorough. For example, Subsection 302 of the bill adds Section (d)(1) to section 4 of the present statute (7 USC 136 b). This subsection specifies the criteria for commercial applicator certification and requires applicants in (B) to "have field or industrial plant experience in pesticide use and application." This requirement of practicial experience would result in a very competent certified applicator.

We also view these new requirements for certification and training as practical and realistic because they satisfy the requirements of the day-to-day operations of a business. For example, Section 302 adds subsection (h) dealing with uniform training to Section 4 (7 USC 136 b). This subsection would allow railway tie workers to work in more than one state:

> "A person shall be considered to have satisfied this section if the person has completed a uniform nationwide course of training for workers that is approved by the Administrator, applies to more than one state, issues credentials to workers on completion, and is subject to verification."

The certification and training sections in S. 2346 reflect the input of many groups that know the value of competent, well-trained pesticide applicators. AWPI also views these sections as necessary to the safe application of pesticides. We therefore urge the Committee to adopt these sections.

Conclusion

The Committee has heard and read a great deal of testimony presented by the FIFRA Coalition. AWPI is an active participant in this group and is supportive of its efforts. The coalition is a broad-based group of organizations representing agricultural user groups, farm groups, urban and rural pesticide user groups and commodity producers as well as manufacturers. Thus, the coalition's bill, S. 2346, addresses many concerns generated about FIFRA.

All members of the FIFRA Coalition share a common goal: pesticides which are safe and effective for their intended uses while posing no unreasonable risks to man and his environment. That goal, and a concerted effort to address impediments to that goal, are reflected in S. 2346. Therefore, the American Wood Preservers Institute urges the committee to support S. 2346.

II

99TH CONGRESS
2D SESSION

S. 2215

To amend the Federal Insecticide, Fungicide, and Rodenticide Act to ensure safer pesticides and to better protect the public and the environment, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 20 (legislative day, MARCH 18), 1986

Mr. LUGAR (for himself, Mr. LEAHY, and Mr. PROXMIRE) introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

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A BILL

To amend the Federal Insecticide, Fungicide, and Rodenticide Act to ensure safer pesticides and to better protect the public and the environment, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE AND TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986".

(b) TABLE OF CONTENTS.—The table of contents is as follows:

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SEC. 2. REFERENCES TO THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT.

Except as otherwise specifically provided, whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.).

TITLE I—PREREGISTRATION ACCESS TO DATA

SEC. 101. PREREGISTRATION ACCESS TO DATA.

(a) IN GENERAL.—Section 3(c) (7 U.S.C. 136a(c)) is amended by adding at the end thereof the following new paragraph:

"(9) PREREGISTRATION ACCESS TO DATA.—

"(A) Prior to the registration of a pesticide, the Administrator shall provide, in accordance with this paragraph, public access to health, safety, and environmental data that are submitted in support of an initial application for the registration of a new active ingredient or initial food use of a previously registered active ingredient.

"(B) The Administrator shall publish in the Federal Register a notice of such application in accordance with paragraph (4).

"(C) Not later than 30 days after the publication of such notice, to obtain access to the data referred to in subparagraph (A), a person must send by certified mail a request for such access and the affirmation referred to in subparagraph (E) simultaneously to the Administrator and to the applicant for the registration of the pesticide.

"(D) Not later than 15 days after receipt of a request for access to such data and affirmation, the Administrator shall grant or deny such request. The Administrator may not extend the 15-day period for acting on such request.

"(E)(i) Notwithstanding any other provision of law, data referred to in subparagraph (A) may be made available only to a person who provides an affirmation (and such supporting evidence as the Administrator considers necessary) that the person is neither employed by nor acting directly or indirectly on behalf of a person or entity engaged or affiliated with a person engaged in the production, sale, or distribution of a pesticide.

"(ii) For purposes of this subparagraph, an affiliate is a person who directly or indirectly, through one or more intermediates, controls or is controlled by or is under common control with the person specified.

"(iii) The affirmation required under clause (i) shall—

"(I) state that the person is neither employed by nor acting on behalf of any business or entity, or affiliate thereof, engaged in the production, sale, or distribution of a pesticide;

"(II) identify any business, employer, or other entity, if any, on whose behalf the person is requesting access to the data; and

"(III) affirm that the person will not intentionally or recklessly violate this paragraph.

"(iv) Section 1001 of title 18, United States Code, shall apply to an affirmation made under this subparagraph.

"(F)(i) Data relating to a pesticide shall be made available to a person only for the purpose of permitting the person to comment to the Administrator on the application for registration of the pesticide.

"(ii) Except as provided in clauses (iii) and (iv), data so obtained may not be—

"(I) published, copied, or transferred to any other individual or entity for use to obtain approval to sell, manufacture, or distribute a pesticide anywhere in the world; and

"(II) may not be used for any purpose in any court or agency of the United States or any State or political subdivision thereof prior to the decision of the Administrator on the registration of the pesticide or after such decision if the application for registration is denied.

"(iii) Data relating to a pesticide may be reasonably quoted in comments submitted to the Administrator. Such comments may not be made public prior to the decision of the Administrator on the registration of the pesticide or after such decision if the application for registration is denied.

"(iv) Such data and comments may be disclosed consistent with section 10 after registration of the pesticide.

"(G)(i) Data relating to a pesticide may be examined at an office of the Environmental Protection Agency or an appropriate State agency that complies with this section and may not be removed from such office.

"(ii) The Administrator shall maintain a record of the persons who inspect data. A copy of the record entry shall be sent to the data submitter.

"(iii) Once access to the data is granted, the data may be examined and comments on the application shall be filed within 60 days, unless extended an additional 30 days for good cause.

"(iv) If access to the data is denied, comments on the application shall be filed within 60 days from the determination of the Administrator denying access.".

(b) NOTICE OF APPLICATION.—Section 3(c)(4) (7 U.S.C. 136a(c)(4)) is amended—

(1) in the first sentence, by striking out "promptly" and inserting in lieu thereof "not later than 30 days"; and

(2) in the second sentence, by striking out "30" and inserting in lieu thereof "60".

SEC. 102. CRIMINAL PENALTIES FOR DISCLOSURE OF INFORMATION.

Paragraph (3) of section 14(b) (7 U.S.C. 136l(b)(3)) is amended to read as follows:

"(3) DISCLOSURE OF INFORMATION.—

"(A) Any person who, with intent to defraud, uses or reveals information relative to the formula of a product acquired under section 3, shall be fined not more than $10,000, or imprisoned for not more than 3 years, or both.

"(B) Any person, including any officer, contractor, or employee of the United States or a State, who—

"(i) is granted access to data under section 3(c)(9); and

"(ii) in furtherance of a commercial purpose involving the production, registration, distribution, or sale of a pesticide—

"(I) knowingly violates such section; or

"(II) knowingly allows data to be made available in violation of such section,

shall be fined not more than $100,000, or imprisoned for not more than 3 years, or both.".

TITLE II—CONDITIONAL REGISTRATION

SEC. 201. CONDITIONAL REGISTRATION.

Subparagraphs (B) and (C) of section 3(c)(7) (7 U.S.C. 136a(c)(7)(B) and (C)) are amended to read as follows:

"(B)(i) The Administrator may conditionally amend the registration of a pesticide to permit additional uses of such pesticide notwithstanding the fact that data concerning the pesticide may be insufficient to support an unconditional amendment, if the Administrator determines that—

"(I) the applicant has submitted all additional data that are required solely for the proposed additional use;

"(II) amending the registration in the manner proposed by the applicant would not materially increase the risk of any unreasonable adverse effect on the environment; and

"(III) the additional use is in the public interest.

"(ii) Notwithstanding clause (i), no registration of a pesticide may be amended to permit an additional use of such pesticide if the Administrator has issued a notice stating that such pesticide, or any ingredient thereof, meets or exceeds risk criteria associated in whole or in part with human dietary exposure specified in regulations issued under this Act.

"(iii) An applicant seeking amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under paragraph (5).

"(iv) Except as provided in clause (v), if the applicant is unable to submit an item of data (other than data pertaining to the proposed additional use) because it has not yet been generated, the Administrator may amend the registration of a pesticide under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this Act.

"(v) If data concerning chronic toxicity (oncogenicity, reproductive effects, and mutagenicity), neurotoxicity, or teratogenicity are required for registration of an additional use of a pesticide that is not a minor use, and such a data requirement was in effect at the time the studies to obtain the data commenced, a conditional registration for such use shall not be granted under this subparagraph unless such data have been submitted.

"(vi) An amendment to an existing conditional registration, other than an amendment for an additional use, may be issued if the registrant has—

"(I) initiated necessary tests to secure such data, even though the data have not been submitted; and

"(II) satisfied the other requirements for the amendment of a conditional registration imposed under this paragraph.

"(C)(i) Except as provided in clauses (ii) and (iii), the Administrator may conditionally register a pesticide containing an active ingredient not contained in any registered pesticide for a period reasonably sufficient for generation and submission of required data (that are lacking because a period reasonably sufficient for generation of the data has not elapsed since the Administrator first imposed the data requirement) if—

"(I) by the end of such period the Administrator receives such data;

"(II) such data do not meet or exceed the risk criteria specified in regulations issued under this Act; and

"(III) such other conditions as the Administrator may prescribe are met.

"(ii) A conditional registration under this subparagraph shall be granted only if the Administrator determines that—

"(I) use of the pesticide during such period will not cause any unreasonable adverse effect on the environment; and

"(II) use of the pesticide is in the public interest.

"(iii) If data concerning chronic toxicity (oncogenicity, reproductive effects, and mutagenicity), neurotoxicity, or teratogenicity are required for registration of the pesticide, and such a data requirement was in effect at the time the studies to obtain the data commenced, a conditional registration shall not be granted under this subparagraph unless such data have been submitted.".

TITLE III—REREGISTRATION AND REVENUES

SEC. 301. DEFINITION OF OUTSTANDING DATA REQUIREMENT.

Section 2 (7 U.S.C. 136) is amended by adding at the end the following new subsection:

"(ff) OUTSTANDING DATA REQUIREMENT.—

"(1) IN GENERAL.—The term 'outstanding data requirement' means any study, required information, or data necessary to make a determination under section 3(c)(5) that—

"(A) has not been submitted to the Administrator; or

"(B) has been submitted to the Administrator but which the Administrator determines are not valid, complete, or adequate to make a determination under section 3 and the regulations and guidelines issued thereunder.

"(2) FACTORS.—In making a determination under paragraph (1)(B), the Administrator shall examine, at a minimum, relevant protocols, documentation of the conduct and analysis of the study, and the results of the study to determine whether the study and the results of the study fulfill the data requirement for which the study was submitted to the Administrator.".

SEC. 302. REREGISTRATION OF PESTICIDES.

Subsection (g) of section 3 (7 U.S.C. 136a(g)) is amended to read as follows:

"(g) REREGISTRATION OF PESTICIDES.—

"(1) IN GENERAL.—The Administrator shall reregister each pesticide in accordance with this subsection.

"(2) LISTS OF PESTICIDE ACTIVE INGREDIENTS.—

"(A) Not later than 60 days after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, the Administrator shall publish in the Federal Register a list of 300 pesticide active ingredients not reregistered since September 30, 1978, in the order of their priority, for reregistration under this Act.

"(B) Not later than 90 days after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, the Administrator shall publish in the Federal Register a list of all pesticide active ingredients remaining after subparagraph (A) that have not been reregistered since September 30, 1978, in the order of their priority, for reregistration under this Act.

"(3) PRIORITY.—In establishing the lists required under paragraph (2), the Administrator shall give the highest priority to pesticides that—

"(A) are in major use on or in food or feed that may result in postharvest residues;

"(B) may result in residues of potential toxicological concern in potable groundwater, edible fish, or shellfish;

"(C) have previously been determined by the Administrator to have the most significant outstanding data requirements; or

"(D) are used on crops, including in greenhouses and nurseries, where worker exposure is most likely to occur.

"(4) REMOVAL.—Not later than 90 days after the publication of a list containing an active ingredient of a pesticide under paragraph (2), the Administrator shall remove such ingredient from the reregistration list if the Administrator is requested by each registrant of each pesticide containing such ingredient that the registration of such pesticide be canceled.

"(5) JUDICIAL REVIEW.—The establishment of a list by the Administrator under this subsection shall not be subject to judicial review.

"(6) DATA REQUIREMENTS.—

"(A) Not later than 18 months after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, the Administrator shall—

"(i) identify and publish in the Federal Register a list of each outstanding data requirement for each pesticide active ingredient referred to in paragraph (2)(A); and

"(ii) simultaneously notify pursuant to subsection (c)(2)(B) each existing registrant of each pesticide containing such ingredient that, in order to maintain the registration of such pesticide under this Act, such registrant must complete studies to fill such outstanding data requirement within a reasonable period of time, but not to exceed 4 years after such notice.

"(B) Not later than 24 months after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, the Administrator shall—

"(i) identify and publish in the Federal Register a list of each outstanding data requirement for each pesticide active ingredient referred to in paragraph (2)(B); and "(ii) simultaneously notify pursuant to subsection (c)(2)(B) each existing registrant of each pesticide containing such ingredient that, in order to maintain the registration of such pesticide under this Act, such registrant must complete studies to fill such outstanding data requirement within a reasonable period of time, but not to exceed 4 years after such notice.

"(C) The Administrator may extend the period referred to in subparagraph (A)(ii) or (B)(ii) by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from filling the outstanding data requirement for a pesticide active ingredient.

"(D) If a hearing is requested following the issuance of such notice, the registrant may appeal in such hearing—

"(i) the classification of a study as an outstanding data requirement; and

"(ii) other matters for resolution referred to in subsection (c)(2)(B)(iv).

"(7) FILLING DATA REQUIREMENTS.—

"(A) Not later than 6 months after issuance of a notice required under paragraph (6) with respect to a pesticide active ingredient, the Administrator shall determine whether appropriate tests have been initiated to fill the identified outstanding data requirements for such ingredient.

"(B) A registrant shall submit annual progress reports to the Administrator that indicate the status of such testing and report interim results.

"(8) SUSPENSION.—The Administrator shall issue a notice of intent to suspend the registration of a pesticide pursuant to subsection (c)(2)(B)(iv) if the Administrator determines that—

"(A) necessary tests to fill an outstanding data requirement for such pesticide have not been initiated within 1 year of the issuance of a notice under paragraph (6);

"(B) progress is insufficient to ensure completion of such tests within the deadlines established in such notice;

"(C) the required test data have not been submitted to the Administrator within the specified deadline; or

"(D) a registrant fails to comply with clauses (ii) and (iii) of subsection (c)(2)(B).

"(9) REREGISTRATION.—

"(A) Not later than 1 year after receipt of the data required by this subsection with respect to a pesticide, the Administrator shall complete reregistration of such pesticide by determining whether such pesticide fulfills the requirements of subsection (c)(5).

"(B) The Administrator shall determine whether a pesticide shall be reregistered under this Act by conducting a thorough examination of all data required by the regulations and guidelines issued pursuant to this section or taking such other steps as are necessary to make such determination.

"(10) FEES.—

"(A) The Administrator shall charge and collect reregistration fees from registrants in accordance with this paragraph.

"(B) To identify outstanding data requirements in accordance with paragraph (6) for each pesticide required to be reregistered under paragraph (2), on issuance of the notice required under subsection (c)(2)(B), the Administrator shall charge and collect from the registrant or registrants of such pesticide a one-time fee of $50,000 for each active ingredient of such pesticide registered for use on food or feed, except that no such fee shall be collected for a pesticide voluntarily canceled in accordance with paragraph (4).

"(C) To subsequently evaluate data and reregister a pesticide in accordance with paragraph (9) for each pesticide required to be reregistered under paragraph (2), on submission of the data required by the notice issued under subsection (c)(2)(B), the Administrator shall collect from the registrant or registrants of such pesticide an additional one-time fee of $100,000 for each active ingredient of such pesticide registered for use on food or feed.

"(D) If an active pesticide ingredient of a pesticide is registered under this Act solely for uses other than for food or feed, the Administrator may levy a reduced fee for the registration of such pesticide, but no less than one-half of the fee charged for an active ingredient of a pesticide registered for use on food or feed.

"(E) On payment of fees for the reregistration of an active ingredient in accordance with this paragraph, the Administrator may not levy any other fees for the reregistration of such ingredient.

"(F) If there are two or more registrants for an active ingredient registered under this Act, the fees shall be apportioned by such registrants in accordance with this section.

"(11) REVOLVING FUND.—

"(A) There shall be established in the Treasury of the United States a revolving fund.

"(B) All fees collected by the Administrator under paragraph (10) shall be deposited into the revolving fund and shall remain available without fiscal year limitation to carry out this subsection.

"(C) Money in the revolving fund not currently needed to carry out this subsection shall be—

"(i) maintained on hand or on deposit;

"(ii) invested in obligations of the United States or guaranteed thereby; or

"(iii) invested in obligations, participations, or other instruments that are lawful investments for fiduciary, trust, or public funds.

"(D) The Administrator shall—

"(i) provide an annual accounting of the fees collected and disbursed from the revolving fund; and "(ii) take all steps necessary to insure that expenditures of such funds are solely utilized to carry out this subsection.

"(12) COMPENSATION OF DATA SUBMITTER.—

"(A) On submission of data or fees required under this subsection, the data submitter shall be compensated in accordance with subsection (c)(1)(D).

"(B) If data or fees are submitted jointly by two or more registrants, an agent shall be appointed by the registrants, at the time of the joint submission or payment of a reregistration fee, to handle any subsequent compensation matters.".

TITLE IV—INERT INGREDIENTS

SEC. 401. DEFINITION OF INGREDIENT STATEMENT.

Subsection (n) of section 2 (7 U.S.C. 136(n)) is amended to read as follows:

"(n) INGREDIENT STATEMENT.—

"(1) IN GENERAL.—The term 'ingredient statement' means a statement that contains—

"(A) the name and percentage of each active ingredient, the name of each inert ingredient listed under section 3(h)(1), and the total percentage of all inert ingredients, in the pesticide; and

"(B) if the pesticide contains arsenic in any form, a statement of the percentages of total and water soluble arsenic, calculated as elementary arsenic.

"(2) COMMON NAME.—An inert ingredient listed under section 3(h)(1) shall be identified by its most common name.".

SEC. 402. COMPENSATION FOR DATA ON INERT INGREDIENTS.

Subparagraph (D) of section 3(c)(2) (7 U.S.C. 136a(c)(2)(D) is amended to read as follows:

"(D) EXEMPTION.—

"(i) No applicant for registration of a pesticide who proposes to purchase a registered pesticide from another producer in order to formulate such purchased pesticide into an end-use product shall be required to—

"(I) submit or cite data pertaining to the safety or such purchased product; or

"(II) offer to pay reasonable compensation otherwise required by paragraph (1)(D) for the use of any such data or reregistration fees.

"(ii) No applicant for registration of a pesticide who proposes to purchase an inert ingredient from another producer in order to formulate the pesticide shall be required to offer to pay reasonable compensation otherwise required by paragraph (1)(D) for a study required to be cited or submitted that was generated pursuant to a data development plan under subsection (h)(7) in accordance with—

"(I) the Toxic Substances Control Act (15 U.S.C. 2601 et seq.); or

"(II) this Act, if the inert ingredient is purchased from a person who is an original data submitter of the study.".

SEC. 403. APPROVAL OF REGISTRATION FOR SUBSTITUTED INERT INGREDIENTS.

(a) APPROVAL OF REGISTRATION.—The first sentence of section 3(c)(5) (7 U.S.C. 136a(c)(5)) is amended—

(1) by striking out "and" at the end of subparagraph (C);

(2) by striking out the period at the end of subparagraph (D) and inserting in lieu thereof "; and"; and

(3) by adding at the end thereof the following new subparagraph:

"(E) in the case of an application to amend a registration to substitute an inert ingredient for an inert ingredient listed under subsection (h)(1), that the requirements of subsection (i) are satisfied.".

(b) Study Requirement.—Section 3(c)(5) is amended by adding at the end thereof the following new sentence: "On or after the date specified for submission of a study in the final data development plan published under subsection (h)(1), an application to register or to amend the registration of a pesticide containing a listed inert ingredient shall be considered not to satisfy the requirements of this paragraph, unless the application is supported by the study required under paragraph (1)(D).".

SEC. 404. PRIORITY LIST AND DATA DEVELOPMENT PLANS FOR INERT INGREDIENTS.

Section 3 (7 U.S.C. 136a) is amended by adding at the end thereof the following new subsection:

"(h) Priority List and Data Development Plans for Inert Ingredients.—

"(1) Establishment of list.—The Administrator shall establish a priority list of inert ingredients consisting of—

"(A) inert ingredients that appear to cause a pesticide to meet or exceed a criterion for initiating an interim administrative review established under subsection (c)(8); and

"(B) inert ingredients for which additional data are reasonably necessary to evaluate whether the inert ingredient may result in a pesticide causing an unreasonable adverse effect on the environment—

"(i) that are similar in molecular structure to a chemical that is oncogenic, mutagenic, teratogenic, or causes another significant adverse effect, and (I) have significant use in pesticides, or (II) to which there is significant exposure from pesticides; or

"(ii) to which there is significant and widespread exposure, or that are in widespread use, in pesticides.

"(2) PUBLICATION OF LIST.—Not later than 90 days after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, the Administrator shall publish the priority list required under paragraph (1). The Administrator shall publish revisions to such list at least annually.

"(3) JUDICIAL REVIEW.—The priority list and any revisions to the priority list shall not be subject to judicial review at the time an initial or revised priority list is published.

"(4) REMOVAL OF INGREDIENTS INVOLVING ADMINISTRATIVE REVIEWS.—An inert ingredient listed on the priority list pursuant to paragraph (1)(A) shall be removed from the priority list on—

"(A) a final decision by the Administrator not to initiate an interim administrative review with respect to any pesticide containing the inert ingredient, or final action by the Administrator concluding interim administrative review, and all actions under section 6 resulting therefrom and judicial review thereof; and

"(B) a final decision by the Administrator under paragraph (7)(F) not to require additional data to be generated, or the receipt and evaluation by the Administrator of all data required to be submitted under paragraph (7), and all actions under section 6 resulting therefrom and judicial review thereof.

"(5) REMOVAL OF INGREDIENTS INVOLVING ADDITIONAL DATA.—An inert ingredient listed on the priority list pursuant to paragraph (1)(B) shall be removed from the priority list on—

"(A) a final decision by the Administrator under paragraph (7)(F) not to require additional data to be generated, and judicial review thereof; or

"(B) the receipt and evaluation by the Administrator of all data required to be generated under paragraph (7), and all actions under section 6 resulting therefrom and judicial review thereof.

"(6) NUMBER OF INGREDIENTS.—The priority list shall consist of not less than 50, and not more than 75, inert ingredients. Initially, the list shall consist of 50 inert ingredients. Twenty-five additional inert ingredients may be added to the list 15 months after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986.

"(7) DATA DEVELOPMENT PLANS.—

"(A) For each inert ingredient referred to in paragraph (1), the Administrator shall publish a proposed data development plan within 1 year after the inert ingredient is placed on the priority list.

"(B) A proposed data development plan for an inert ingredient shall include—

"(i) a discussion of the risk concerns raised by the inert ingredient and the anticipated exposures to man and the environment from the use of the ingredient in pesticides;

"(ii) in the case of an inert ingredient referred to in paragraph (1)(A)—

"(I) the studies that the Administrator proposes to require to address the concerns identified pursuant to clause (i); or

"(II) if the Administrator proposes not to require additional studies, a discussion of the reasons for not requiring any additional studies;

"(iii) in the case of an inert ingredient referred to in paragraph (1)(B), the studies that the Administrator proposes to require to address the concerns identified pursuant to clause (i);

"(iv) the regulatory mechanisms or other procedures the Administrator proposes to use to generate the studies; and

"(v) the dates for submission of the studies, as established in accordance with subparagraph (C).

"(C)(i) Subject to clause (ii), a proposed data development plan shall require the submission of the studies referred to in subparagraph (B) within a reasonable time, not to exceed 4 years after the issuance of the final data development plan.

"(ii) The Administrator may extend such period by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the submission of necessary studies.

"(D) In preparing a proposed data development plan, the Administrator shall consider—

"(i) the minor use factors referred to in subsection (c)(2)(A);

"(ii) the guidelines published pursuant to such subsection;

"(iii) the use of a tiered testing program, under which the need for long-term studies would be evaluated after receipt of short-term studies;

"(iv) the use of other statutory authorities of the Administrator to require the generation of the identified studies on an equitable basis, considering nonpesticide uses, and within the dates specified in the data development plan; and

"(v) data generated or scheduled for generation.

"(E) The Administrator shall allow 60 days for registrants and interested members of the public to comment on the proposed data development plan.

"(F)(i) Not later than 30 days after the close of the comment period, the Administrator shall publish a final data development plan or a final decision to require no additional studies.

"(ii) The final data development plan and label requirement imposed under subsection (j)(1), or a final decision to require no additional studies, shall be subject to judicial review under section 16 at the time the final data development plan is published.

"(iii) The omission of an inert ingredient from the priority list established under paragraph (1) shall be subject to judicial review under section 16 at any time after the first data development plan is published.

"(G)(i) The Administrator shall take appropriate action to implement the final data development plan at the same time as the publication of the plan, including, as appropriate, the issuance of notices under subsection (c)(2)(B).

"(ii) If a hearing is requested by a registrant under subsection (c)(2)(B)(iv), the registrant may contest whether the Administrator has complied with subparagraphs (B) and (D).

"(H) On receipt of the additional data for each inert ingredient submitted pursuant to subparagraph (G), the Administrator shall, within 1 year, evaluate the data and take such steps as are appropriate to prevent unreasonable adverse effects on the environment of pesticides containing such inert ingredient.

"(I)(i) For purposes of subsection (c)(1)(D)—

"(I) any study that, pursuant to a data development plan, was generated other than with public funds using another statutory authority of the Administrator, shall be treated as having been submitted in support of registration; and

"(II) the person who submitted the study shall be treated as an original data submitter.

"(ii) For purposes of subsection (c)(1)(D)(iii), the compensation period for a study generated using the Toxic Substances Control Act (15 U.S.C. 2601 et seq.) shall expire at the expiration of the reimbursement period provided for in section 4(c)(3)(B) of such Act (15 U.S.C. 2603(c)(3)(B)).".

SEC. 405. SUBSTITUTION OF INERT INGREDIENTS.

Section 3 (7 U.S.C. 136a) (as amended by section 404 of this Act) is amended by adding at the end thereof the following new subsection:

"(i) SUBSTITUTION OF INERT INGREDIENTS.—The Administrator shall approve an application to amend the registration of a pesticide to substitute an inert ingredient for an inert ingredient listed under subsection (h)(1), if the Administrator finds, on the basis of similarity in molecular structure to a chemical known to cause significant adverse effects, existing data, or such short-term tests as the Administrator determines are necessary, that the substitute inert ingredient does not pose the same or similar concerns about unreasonable adverse effects on the environment that resulted in the listing of the original inert ingredient.".

SEC. 406. LABELING OF INERT INGREDIENTS.

Section 3 (7 U.S.C. 136a) (as amended by section 405 of this Act) is amended by adding at the end thereof the following new subsection:

"(j) LABELING OF INERT INGREDIENTS.—

"(1) AMENDED LABEL.—Not later than 30 days after the publication of a final data development plan under subsection (h)(7)(F), the registrant of a pesticide that contains the listed inert ingredient shall apply for an amended registration of the pesticide to change the label of the pesticide to conform with subsections (q)(2)(A) and (n) of section 2. Not later than 30 days after receipt of such application, the Administrator shall act on such application.

"(2) MISBRANDING.—A pesticide, the ingredient statement of which does not satisfy section 2(n) with respect to a listed inert ingredient, shall not be considered misbranded until 120 days after the publication of the data development plan or the date on which the Administrator approves a registration amendment providing for a change in the label of the pesticide to satisfy section 2(n), whichever occurs later.".

SEC. 407. FORMULA STATEMENTS.

Section 3 (7 U.S.C. 136a) (as amended by section 406 of this Act) is amended by adding at the end thereof the following new subsection:

"(k) FORMULA STATEMENTS.—

"(1) LISTED INERT INGREDIENTS.—Not later than 120 days after the initial publication of the priority list required pursuant to subsection (h)(1), each registrant of a pesticide containing an inert ingredient or ingredients contained on the list shall make any neces-

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sary modifications to the formula statement submitted pursuant to subsection (c)(1)(E) to satisfy the requirements of the Administrator with respect to such ingredient or ingredients.

"(2) ALL INERT INGREDIENTS.—Not later than 240 days after the initial publication of the priority list required pursuant to subsection (h)(1), each registrant of a pesticide containing an inert ingredient or ingredients shall make any necessary modifications to the formula statement submitted pursuant to subsection (c)(1)(E) to satisfy the requirements of the Administrator with respect to such ingredient or ingredients.".

SEC. 408. DISCLOSURE OF INERT INGREDIENTS.

(a) DISCLOSURE PERMITTED.—Section 10(d)(1)(C) (7 U.S.C. 136h(d)(1)(C)) is amended by inserting before the period the following: ", except that the identity of an inert ingredient listed under section 3(h)(1) shall be disclosed in accordance with paragraph (4)".

(b) METHODS.—Section 10(d) is amended by adding at the end thereof the following new paragraph:

"(4)(A) The identity of an inert ingredient may be disclosed by—

"(i) the listing of the ingredient on the priority list required by section 3(h)(1); and "(ii) the release of product labels disclosing the identity of an inert ingredient on the priority list.

"(B) The Administrator may continue to require identification of an inert ingredient on the product label pursuant to section 2(n) after the removal of the ingredient from the priority list pursuant to paragraph (4) or (5) of section 3(h) if the Administrator has issued a notice under section 3(c)(8) or 6.".

TITLE V—PUBLIC RIGHT TO KNOW

SEC. 501. REGISTRATION STATEMENTS.

Section 3(c)(1) (7 U.S.C. 136a(a)(1)) is amended—

(1) by striking out "and" at the end of subparagraph (E);

(2) by striking out the period at the end of subparagraph (F) and inserting in lieu thereof a semicolon; and

(3) by adding at the end thereof the following new subparagraphs:

"(G)(i) proposed fact sheets that contain—

"(I) the name of the pesticide active ingredients and inert ingredients referred to in subsection (h)(1); and

"(II) a summary of relevant health, safety, and environmental data.

"(ii) Not later than 120 days after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, each registrant of a pesticide active ingredient, or pesticide containing an inert ingredient referred to in subsection (h)(1), that is registered on the effective date of such Act shall submit the fact sheets required under this subparagraph to the Administrator.

"(iii) A fact sheet required under this subparagraph for a registered pesticide shall be--

"(I) maintained and kept current by a registrant; and

"(II) made available to the public, on request, by the Administrator and the registrant.

"(iv) The Administrator may require amendments to such fact sheets in order to provide accurate and clear information to the public; and

"(H)(i) a list of locations where the pesticide of the registrant will be produced in the United States.

"(ii) Not later than 120 days after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, each registrant of a pesticide active ingredient that is registered on the effective date of such Act shall submit a list of locations where the registrant produces the pesticide in the United States.

"(iii) On approval of the registration of the pesticide, such list shall be—

"(I) maintained and kept current by a registrant; and

"(II) made available to the public, on request, by the Administrator and the registrant.".

SEC. 502. REGISTRATION OF ESTABLISHMENTS.

(a) CONFIDENTIAL RECORDS AND INFORMATION.—Section 7(d) (7 U.S.C. 136e(d)) is amended by inserting "and production locations" after "names".

(b) FACT SHEETS.—Section 7 is amended by adding at the end thereof the following new subsection:

"(e) FACT SHEETS.—Any producer operating an establishment registered under this section shall obtain and make available to the public a fact sheet required under section 3(c)(1)(G) for each active ingredient and listed inert ingredient used in the establishment.".

TITLE VI—DATA DISCLOSURE TO STATES

SEC. 601. DATA DISCLOSURE TO STATES.

Section 10 (7 U.S.C. 136h) is amended by adding at the end thereof the following new subsection:

"(h) DATA DISCLOSURE TO STATES.—

"(1) IN GENERAL.—The Administrator may disclose to a State any data or information acquired under this Act if the State assures the Administrator and the Administrator determines that the owner of the data or information will receive no less protection with respect to the disclosure and use of the data or information by the State than is provided by section 3 and this section.

"(2) ACTION FOR JUST COMPENSATION.—For the purpose of any action that may lie against the United States for just compensation under section 1491 of title 28, United States Code—

"(A) the disclosure or use of data or information provided by the Administrator to a State in a manner inconsistent with this section or section 3 shall be considered a taking of property; and

"(B) the act of a State with respect to such data or information shall be considered an act of the United States.".

TITLE VII—CANCELLATION PROCEDURES

SEC. 701. INTERIM ADMINISTRATIVE REVIEW.

(a) INTERIM ADMINISTRATIVE REVIEW.—Paragraph (8) of section 3(c) (7 U.S.C. 136a(c)(8)) is amended to read as follows:

"(8) INTERIM ADMINISTRATIVE REVIEW.—

"(A) CRITERIA.—

"(i) Notwithstanding any other provision of this Act, the Administrator may not initiate a public interim administrative review process to develop a risk-benefit evaluation of the ingredients of a pesticide or any of its uses prior to initiating a formal action to cancel, suspend, or deny registration of such pesticide, required under this Act, unless such interim administrative process is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or to the environment.

"(ii) The Administrator shall publish in the Federal Register notice of the definition of the terms 'validated test' and 'other significant evidence' as used in this subparagraph.

"(iii) Criteria for initiating an interim administrative review shall be established on the basis of levels of risk, and may include consideration of currently available exposure data.

"(iv) Absence of exposure data shall not delay or preclude initiation of an interim administrative review. The Administrator shall not decline to initiate an interim administrative review solely on the basis of exposure unless adequate data on all relevant means of exposure have been considered.

"(v) On receipt of data demonstrating that interim administrative review triggers are exceeded, the Administrator shall immediately notify all registrants of the pesticide and provide the registrants with appropriate information and an explanation of the manner in which the trigger has been exceeded.

"(vi) Not later than 30 days after receipt of such notice, a registrant may respond to such notice.

"(vii) Not later than 30 days after the Administrator receives a response from a registrant, the Administrator shall determine whether an interim administrative review of the pesticide shall be initiated.

"(B) PROCEDURES.—

"(i) Notice of an interim administrative review shall be provided to all registrants and interested members of the public and shall be published in the Federal Register.

"(ii) The notice shall state the basis for the review, indicate the availability of all data on which the position of the Administrator is based, and include a request for any additional data needed for the review.

"(iii) Not later than 90 days after publication of a notice of such review, comments may be submitted on such review.

"(iv) Not later than 90 days after the close of the comment period, the Administrator shall review all comments and additional data submitted and shall publish a proposed regulatory position.

"(v) Not later than 45 days after the close of the initial comment period, additional comments may be submitted to the Administrator to address comments filed by other parties.

"(vi)(I) The proposed regulatory position of the Administrator shall be submitted to the Scientific Advisory Panel established under section 25(d) at the next scheduled meeting of the panel for comment solely on relevant scientific issues. The public may submit comments to the Scientific Advisory Panel concerning such position.

"(II) Not later than 30 days after such meeting, the Scientific Advisory Panel shall issue a report on such position.

"(III) The Administrator shall review and consider the report of the Scientific Advisory Panel.

"(IV) Not later than 60 days after receipt of such report, the Administrator shall issue a final regulatory decision whether to retain, restrict, or cancel the uses of the pesticide.

"(vii) Not later than 1 year after the initiation of a review, the Administrator shall make such decision.

"(viii) The time limits specified in this paragraph may not be extended, except in exceptional circumstances in which—

"(I) additional data critical to a fair and accurate determination of risks posed by the pesticide are required;

"(II) the extension is for a period limited to the time required to obtain such data on an expedited basis and in no event to exceed 1 year; and

"(III) the Administrator acted to obtain the additional data at the time the interim administrative review was initiated.".

(b) SCIENTIFIC ADVISORY PANEL.—The first sentence of section 25(d) (7 U.S.C. 136w(d)) is amended by striking out "The" and inserting in lieu thereof "Except when a referral is made pursuant to section 3(c)(8)(B) to the Scientific Advisory Panel established by this subsection, the".

(c) APPLICATION OF AMENDMENTS.—The amendments made by this section shall apply to interim administrative reviews under section 3(c)(8) initiated after January 1, 1986.

SEC. 702. CANCELLATION AND CHANGE IN CLASSIFICATION.

Subsection (b) of section 6 (7 U.S.C. 136d(b)) is amended to read as follows:

"(b) CANCELLATION AND CHANGE IN CLASSIFICATION.—

"(1) NOTICE.—

"(A) Subject to subparagraph (B), if it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with this Act or when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment, the Administrator may issue a notice of the intent of the Administrator—

"(i) to cancel its registration or to change its classification together with the reasons (including the factual basis) for the action of the Administrator; or

"(ii) to hold a hearing to determine whether or not its registration should be canceled or its classification changed.

"(B)(i) The Administrator may require changes to the labeling of a pesticide by informal rulemaking unless the changes are equivalent to a cancellation of a use, render the product unmarketable, or otherwise have a major economic impact on the product, in which case the changes shall be subject to the hearing procedures provided in this section.

"(ii) Label changes issued through informal rulemaking shall not be effective pending any judicial review requested under section 16 after a final order of the Administrator.

"(C) Notice shall be sent to the registrant and made public.

"(D) The notice shall include the findings and conclusions in support of the proposed action.

"(E) In determining whether to issue any such notice, the Administrator shall include among those factors to be taken into account the impact of the action proposed in such notice on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy.

"(F)(i) Not later than 60 days prior to sending such notice to the registrant or making public such notice, whichever occurs first, the Administrator shall provide the Secretary of Agriculture with a copy of such notice and an analysis of such impact on the agricultural economy.

"(ii) If the Secretary comments in writing to the Administrator regarding the notice and analysis within 30 days after receiving them, the Administrator shall publish in the Federal Register (with the notice) the comments of the Secretary and the response of the Administrator with regard to the comments of the Secretary.

"(iii) If the Secretary does not comment in writing to the Administrator regarding the notice and analysis within 30 days after receiving them, the Administrator may notify the registrant and make public the notice at any time after such 30-day period notwithstanding the 60-day time requirement imposed by clause (i).

"(iv) The time requirements imposed by this subparagraph may be waived or modified to the extent agreed on by the Administrator and the Secretary.

"(G) Notwithstanding any other provision of this subsection and section 25(d), in the event that the Administrator determines that suspension of a pesticide registration is necessary to prevent an imminent hazard to human health, on such a finding, the Administrator may waive the requirement of notice to and consultation with the Secretary of

Agriculture pursuant to this subsection and of submission to the Scientific Advisory Panel pursuant to section 25(d) and proceed in accordance with subsection (c).

"(2) HEARING.—

"(A) The proposed action shall become final and effective at the end of 30 days from receipt by the registrant, or publication of a notice issued under paragraph (1)(A)(i), whichever occurs later, unless within that time—

"(i) the registrant makes the necessary corrections, if possible; or

"(ii) a request for a hearing is made by a person adversely affected by the notice.

"(B) Whenever a request for a hearing is made, the request shall—

"(i) identify with particularity the findings and conclusions of the decision of the Administrator that are disputed; and

"(ii) include a complete statement of the reasons and factual basis that support the request for a hearing.

"(C) Another party to the proceeding may also identify findings and conclusions in dispute.

"(D) If a hearing is held pursuant to such a request or the determination of the Administrator under paragraph (1)(A)(ii), a decision pertaining to registration or classification issued after completion of such hearing shall be final.

"(3) FACTORS.—In taking any action under this subsection, the Administrator shall—

"(A) consider restricting a use or uses of a pesticide as an alternative to cancellation and fully explain the reasons for such restrictions; and

"(B) include among those factors to be taken into account the impact of such final action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and publish in the Federal Register an analysis of such impact.".

SEC. 703. PUBLIC HEARINGS AND SCIENTIFIC REVIEW.

Section 6(d) (7 U.S.C. 136d(d)) is amended—

(1) by striking out the fifth through ninth sentences; and

(2) in the tenth sentence, by striking out "90 days thereafter" and inserting in lieu thereof "12 months after issuance of the notice that gave rise to the hearing, or such shorter time specified in subsection (g)(4),".

SEC. 704. HEARING FOLLOWING INTERIM ADMINISTRATIVE REVIEW.

Section 6 (7 U.S.C. 136d) is amended by adding at the end thereof the following new subsection:

"(g) HEARING FOLLOWING INTERIM ADMINISTRATIVE REVIEW.—

"(1) IN GENERAL.—If a hearing is held following an interim administrative review of a pesticide conducted pursuant to section 3(c)(8), the procedures set forth in subsections (b) and (d) shall be modified in accordance with this subsection.

"(2) REQUEST FOR HEARING.—Any person who is adversely affected by a decision of the Administrator following an interim administrative review may request a hearing within 30 days of such decision or failure to make a decision.

"(3) JUDICIAL REVIEW.—Any person may seek judicial review under section 16(a) of the failure of the Administrator to make a decision within the time required under section 3(c)(8).

"(4) PROCEDURES.—

"(A) At the request of a party, a hearing examiner may receive into evidence portions of the interim administrative review record that the party demonstrates are relevant and material to the disputed issues.

"(B) The right of other parties to confront and cross-examine such evidence shall be preserved with respect to material issues of adjudicative fact, so long as such cross examination is not unduly repetitious.

"(C) Not later than 60 days after the hearing examiner is appointed, prehearing matters shall be completed and the hearing shall commence.

"(D) Not later than 30 days before the hearing commences, the parties shall exchange witness lists and exhibits to be offered at the hearing.

"(E) If studies become available that were not considered during the interim administrative review, the hearing examiner may, on request of any party and when in the judgment of the hearing examiner it is necessary, submit such studies to the Scientific Advisory Panel established under section 25(d) for supplemental comment on an expedited basis, except that such comment shall not extend the time for completion of the hearing.

"(F) The hearing examiner shall schedule the presentation and examination of witnesses so that the presentation of evidence is completed within 60 days, except that the schedule shall not prejudice the right of a party to present evidence.

"(G) The parties shall submit briefs within 20 days of receiving a transcript of the hearing.

"(H) The hearing examiner shall render a recommended decision within 20 days from the submission of briefs by the parties.

"(I) A hearing conducted under this section shall be completed and the Administrator shall make a final decision within 6 months of the issuance of the notice that gave rise to the hearing.

"(J) The time limits imposed by this subsection may not be extended, except in exceptional circumstances in which it is essential for a fair and accurate determination of pivotal facts central to the proceeding, and in no event to exceed 180 days.".

TITLE VIII—FALSE OR INVALID DATA

SEC. 801. CANCELLATION OF REGISTRATION BASED ON FALSE OR INVALID DATA.

Section 6 (7 U.S.C. 136d) (as amended by section 704 of this Act) is amended by adding at the end thereof the following new subsection:

"(h) CANCELLATION OF REGISTRATION BASED ON FALSE OR INVALID DATA.—

"(1) NOTICE.—The Administrator shall immediately issue a notice of intent to suspend and to cancel the registration of a pesticide if—

"(A) prior to the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, the Administrator has previously determined in the Industrial Biotest validation process conducted by the Administrator that data submitted by a registrant to the Administrator in support of such registration were invalid;

"(B) the data—

"(i) have not been replaced on the effective date of such Act; or

"(ii) are in the process of being replaced on the effective date of such Act but have not been submitted to the Administrator by April 1, 1988; and

"(C) the data are material to the registration.

"(2) INVALID DATA.—If, after the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, the Administrator determines that invalid data have been submitted by a registrant to the Administrator in support of a registration of a pesticide, the Administrator may—

"(A) require the registrant to submit valid replacement studies or data on an expedited schedule and to submit interim progress reports; or

"(B) issue a notice of intent to cancel such registration, if the Administrator determines that such action would be in the public interest, taking into account the scope of the invalid data and the need to use the data to determine whether the pesticide may cause unreasonable adverse effects on the environment.

"(3) FALSE DATA.—If a registrant willfully submits material data known to be false in support of the registration of a pesticide, the Administrator shall immediately issue a notice of intent to suspend and cancel such registration.

"(4) HEARING.—

"(A) Any suspension or cancellation under this subsection shall become final and effective at the end of the 30-day period beginning on receipt by the registrant of a notice issued under this section unless during such period a request for a hearing is made by a person adversely affected.

"(B) A hearing under this paragraph shall be conducted in accordance with subsection (c) or (d), as appropriate.

"(C) The only matters for resolution at a hearing conducted pursuant to paragraph (1) shall be whether—

"(i) in response to a notice of the Administrator issued under section 3(c)(2)(B) or other formal notice, data previously determined by the Administrator to be invalid—

"(I) have not been replaced on the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986; or

"(II) are in the process of being replaced on the effective date of such Act but have not been submitted to the Administrator by April 1, 1988; and

"(ii) the data are material to the registration.

"(D) The only matters for resolution at a hearing conducted pursuant to paragraph (2) shall be whether data are invalid, material, and necessary to adequately determine whether a pesticide may cause unreasonable adverse effects on the environment.

"(E) The only matters for resolution at a hearing conducted pursuant to paragraph (3) shall be whether a registrant willfully submitted material data known to be false.

"(F) A decision after completion of a hearing conducted under this paragraph shall be final.

"(G) Notwithstanding any other provision of this Act, a hearing shall be held, and a determination made, under this subsection within 75 days after the receipt of a request for such hearing.".

SEC. 802. UNLAWFUL ACTS INVOLVING FALSE DATA.

Section 12(a)(2) (7 U.S.C. 136j(a)(2)) is amended—

(1) by striking out "or" at the end of subparagraph (O);

(2) by striking out the period at the end of subparagraph (P) and inserting in lieu thereof "; or"; and

(3) by adding at the end thereof the following new subparagraph:

"(Q) to willfully falsify all or part of any data submitted pursuant to this Act, or to willfully submit such false data knowing it to be false.".

TITLE IX—INSPECTION OF LABORATORIES

SEC. 901. INSPECTION OF LABORATORIES.

Section 9(a) (7 U.S.C. 136g(a)) is amended by inserting after the first paragraph the following new paragraph:

"For purposes of verifying the accuracy of data submitted in support of an experimental use permit or registration, an officer or employee duly designated by the Administrator is authorized, after the submission of an application for an experimental use permit under section 5 or an application for a registration under section 3, to enter at reasonable times any laboratory to inspect relevant parts of such laboratory, related books and records, and data that have been or are being developed to support such application. The Administrator shall coordinate actions taken under this section with actions taken under other Federal laws for the purpose of avoiding duplication of inspections.".

TITLE X—EXPORT OF PESTICIDES

SEC. 1001. DEFINITION OF MISBRANDED.

Section 2(q)(1) (7 U.S.C. 136(q)(1)) is amended—

(1) by striking out "or" at the end of subparagraph (G);

(2) by striking out the period at the end of subparagraph (H) and inserting in lieu thereof "; or"; and

(3) by adding at the end thereof the following new subparagraph:

"(I) in the case of a pesticide intended for export that is substantially similar in composition and use pattern to a pesticide registered under section 3, the label does not contain the same health, safety, and hazard precautions as a pesticide registered under section 3, unless such precautions on the label are in conflict with the law of the importing country.".

SEC. 1002. DEFINITION OF IMPORTING COUNTRY.

Section 2 (7 U.S.C. 136) (as amended by section 301 of this Act) is amended by adding at the end thereof the following new subsection:

"(gg) IMPORTING COUNTRY.—The term 'importing country' means the first country to which a pesticide, device, or active ingredient, subject to the notification requirement of section 17(a), is exported from the United States.".

SEC. 1003. BOOKS AND RECORDS.

The first sentence of section 8(a) (7 U.S.C. 136f(a)) is amended by inserting "and exporters" after "producers".

SEC. 1004. PESTICIDES AND DEVICES INTENDED FOR EXPORT.

(a) IN GENERAL.—Subsection (a) of section 17 (7 U.S.C. 136o(a)) is amended to read as follows:

"(a) PESTICIDES AND DEVICES INTENDED FOR EXPORT.—

"(1) VIOLATIONS.—Notwithstanding any other provision of this Act, no pesticide or device or active ingredient used in producing a pesticide intended solely for export to any foreign country shall be considered in violation of this Act when prepared or packed according to the specifications or directions of the foreign purchaser, except that producers of such pesticides and devices and active ingredients used in producing pesticides shall be subject to sections 2(p), 2(q)(1) (A), (C), (D), (E), (G), (H), and (I), 2(q)(2) (A), (B), (C) (i) and (iii), and (D), 7, 8, and 17(a) (2), (3), (4), (5), and (6).

"(2) EXPORTS.—

"(A) This paragraph applies to a pesticide, device, or active ingredient

"(i) for which a restricted use classification has become effective under section 3;

"(ii) for which a cancellation or suspension has become effective under section 6;

"(iii) the registration of which has been voluntarily withdrawn by the registrant, if such withdrawal was associated with concern over potential adverse public health or environmental effects; or

"(iv) that is not registered under section 3 for any use.

"(B) No pesticide, device, or active ingredient described in subparagraph (A) may be exported to any foreign country by any person unless, at least 30 days prior to the first shipment each year of such pesticides to such country, such person has—

"(i) notified, pursuant to paragraph (3), the person importing the pesticide and the appropriate government regulatory office in the importing country;

"(ii) received written evidence that the notification was delivered to the appropriate government regulatory office; and

"(iii) submitted a copy of the notification in English and evidence of delivery to the Administrator.

"(C) Documents referred to in subparagraph (B) shall be made available to the public, on request.

"(3) NOTIFICATION.—The notification required pursuant to paragraph (2) shall be made in an appropriate language and shall contain the following information—

"(A) the name of the pesticide and the common and chemical names of the active ingredient;

"(B) the name and address of the person exporting the pesticide;

"(C) the name and address of the person importing the pesticide;

"(D) the name and address of the appropriate government regulatory office in the importing country;

"(E) a statement of the reasons why the pesticide was canceled, suspended, voluntarily withdrawn, is not registered in the United States, or has been classified for restricted use, and the list of restrictions; and

"(F) the name and address of the office of the United States Environmental Protection Agency that, on request by the importer or official of the importing country, can provide additional information on the pesticide.

"(4) LABELS.—

"(A) The label of pesticides intended for export from the United States shall be written in an appropriate language.

"(B) Except as provided in section 2(q)(1)(H), such label may not refer to compliance with the laws of the United States unless the label also contains or is accompanied by a description of the relevant requirements of such laws.".

(b) EFFECTIVE DATES.—

(1) Section 17(a) (2) and (3) (as amended by subsection (a) of this section) shall become effective 90 days after the date of enactment of this Act.

(2) Not later than 30 days after the date of enactment of this Act, the Administrator of the Environmental Protection Agency shall publish in the Federal Register a list of the names, addresses, and international telecommunications codes of appropriate regulatory offices required to receive notices under section 17(a)(2)(B).

(3) Not later than 180 days after the date of enactment of this Act, and annually thereafter, the Administrator shall revise the list required under paragraph (2).

(4) Not later than 90 days after the date of enactment of this Act, the Administrator shall publish in the Federal Register preliminary guidelines regarding—

(A) the form of the notification required under section 17(a)(2);

(B) translation of the notification and labels required under such section into the appropriate language;

(C) retention of shipping documents and other pertinent records by exporters under such section; and

(D) procedures for public access to documents submitted by exporters under such section.

(5) Not later than 1 year after the date of enactment of this Act, the Administrator shall issue such regulations as are necessary to carry out section 17(a) (2) and (3) and this subsection.

SEC. 1005. CANCELLATION NOTICES FURNISHED TO FOREIGN GOVERNMENTS.

Subsection (b) of section 17 (7 U.S.C. 136o(b)) is amended as follows:

"(b) CANCELLATION NOTICES FURNISHED TO FOREIGN GOVERNMENT.—

"(1) ISSUANCE.—The Administrator shall transmit through the State Department a notice, at such time and annually thereafter, to the appropriate governmental regulatory office of other countries and to appropriate international agencies whenever—

"(A) a registration, or a cancellation or suspension of the registration, of a pesticide becomes effective, or ceases to be effective; or

"(B) a pesticide is classified for restricted use.

"(2) CONTENTS.—Such notification shall include—

"(A) the reasons for the regulatory action taken;

"(B) for canceled or suspended registrations, information concerning other pesticides that are registered under section 3 and that could be used in lieu of such pesticide; and

"(C) the name and address of the office of the United States Environmental Protection Agency that, on request, can provide additional information on the pesticide.".

SEC. 1006. COOPERATION IN INTERNATIONAL EFFORTS.

Subsection (d) of section 17 (7 U.S.C. 136o(d)) is amended to read as follows:

"(d) COOPERATION IN INTERNATIONAL EFFORTS.—The Administrator shall—

"(1) in cooperation with the Department of State, other appropriate Federal agencies, and non-governmental and international organizations, actively participate in international efforts to develop improved pesticide research and regulatory programs;

"(2) provide foreign countries with technical assistance to develop comprehensive pesticide regulatory programs;

"(3) within 1 year of the effective date of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1986, and every 3 years thereafter, conduct and publish a survey of all countries that import pesticides from United States exporters or from which the United States imports agricultural commodities, to—

"(A) ascertain what procedures are in place in each country regarding registration, labeling, and training to ensure safe handling, transportation, application, and disposal of pesticides; and

"(B) control residues on foods in order to meet tolerances established under United States law; and

"(4) report to Congress annually on the activities conducted to comply with this subsection and the results thereof.".

SEC. 1007. TOLERANCES FOR AGRICULTURAL COMMODITIES.

Section 17 (7 U.S.C. 136o) is amended by adding at the end thereof the following new subsection:

"(f) TOLERANCES FOR AGRICULTURAL COMMODITIES.—

"(1) REGISTRATION.—Subject to paragraph (2), if the registration of a pesticide under this Act has been canceled, suspended, denied, or voluntarily withdrawn (unless any such action was due solely to environmental effects), the Administrator shall, not later than 60 days after such action, revoke or amend—

"(A) the corresponding tolerance or exemption from tolerance established under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a); and

"(B) any food additive regulation established under section 409 of such Act (21 U.S.C. 348).

"(2) AMENDMENT OF TOLERANCE.—The Administrator may amend such tolerance only to permit food in commerce that contains residues of the pesticide from previously registered uses, from foreign or United States use of existing stocks permitted under section 6(a), or from unavoidable residual environmental contamination.

"(3) LOWERING OF TOLERANCE.—The Administrator shall promptly lower any such amended tolerance as soon as such residues decrease.".

TITLE XI—AUTHORIZATION FOR APPROPRIATIONS

SEC. 1101. AUTHORIZATION FOR APPROPRIATIONS.

Effective October 1, 1986, section 31 (7 U.S.C. 136y) (as amended by section 1768 of the Food Security Act of 1985 (Public Law 99-198)) is amended to read as follows:

"SEC. 31. AUTHORIZATION FOR APPROPRIATIONS.

"There is authorized to be appropriated to carry out this Act $100,000,000 for the fiscal year ending September 30, 1987, $110,000,000 for the fiscal year ending September 30, 1988, $70,000,000 for the fiscal year ending September 30, 1989, and $70,000,000 for the fiscal year ending September 30, 1990.".

TITLE XII—EMPLOYEE PROTECTION

SEC. 1201. EMPLOYEE PROTECTION.

The Act (7 U.S.C. 136 et seq.) is amended by adding at the end thereof the following new section:

"SEC. 32. EMPLOYEE PROTECTION.

"(a) IN GENERAL.—No employer may discharge any employee or otherwise discriminate against any employee with respect to the employee's compensation, terms, conditions, or privileges of employment because the employee (or any person acting pursuant to a request of the employee) has—

"(1) commenced, caused to be commenced, or is about to commence or cause to be commenced a proceeding under this Act;

"(2) testified or is about to testify in any such proceeding; or

"(3) assisted or participated, or is about to assist or participate, in any manner in such a proceeding or in any other action to carry out the purposes of this Act.

"(b) ADMINISTRATION.—The Administrator shall implement this section in a manner consistent with the procedures, remedies, review, enforcement, and exclusion provisions of section 23 of the Toxic Substances Control Act (15 U.S.C. 2622).".

TITLE XIII—TECHNICAL AMENDMENTS

SEC. 1301. TABLE OF CONTENTS.

The table of contents contained in section 1(b) (7 U.S.C. prec. 121) is amended—

(1) by striking out the item relating to section 2(n) and inserting in lieu thereof the following:

"(n) Ingredient statement.
    "(1) In general.
    "(2) Common name.";

(2) by adding at the end of the items relating to section 2 the following:

"(ff) Outstanding data requirement.
    "(1) In general.
    "(2) Factors.
"(gg) Importing country.";

(3) by striking out the item relating to section 3(c)(8) and inserting in lieu thereof the following:

"(8) Interim administrative review.
"(A) **Criteria.**
"(B) **Procedures.**";

(4) by adding at the end of the items relating to section 3(c) the following:

"(9) Preregistration access to data.";

(5) by striking out the item relating to section 3(g) and inserting in lieu thereof the following:

"(g) Reregistration of pesticides.
"(1) **In general.**
"(2) **Lists of pesticide active ingredients.**
"(3) **Priority.**
"(4) **Removal.**
"(5) **Judicial review.**
"(6) **Data requirements.**
"(7) **Filling data requirements.**
"(8) **Suspension.**
"(9) **Reregistration.**
"(10) **Fees.**
"(11) **Revolving fund.**
"(12) **Compensation of data submitter.**";

(6) by adding at the end of the items relating to section 3 the following:

"(h) Priority list and data development plans for inert ingredients.
"(1) **Establishment of list.**
"(2) **Publication of list.**
"(3) **Judicial review.**
"(4) **Removal of ingredients involving interim administrative reviews.**
"(5) **Removal of ingredients involving additional data.**
"(6) **Number of ingredients.**
"(7) **Data development plans.**
"(i) Substitution of inert ingredients.
"(j) Labeling of inert ingredients.
"(1) **Amended label.**
"(2) **Misbranding.**
"(k) Formula statements.
"(1) **Listed inert ingredients.**
"(2) **All inert ingredients.**";

(7) by striking out the item relating to section 6(b) and inserting in lieu thereof the following:

"(b) Cancellation and change in classification.
  "(1) Notice.
  "(2) Hearing.
  "(3) Factors.";

(8) by adding at the end of the items relating to section 6 the following:

"(g) Hearing following interim administrative review.
  "(1) In general.
  "(2) Request for hearing.
  "(3) Judicial review.
  "(4) Procedures.
"(h) Cancellation of registration based on false or invalid data.
  "(1) Notice.
  "(2) Invalid data.
  "(3) False data.
  "(4) Hearing.";

(9) by adding at the end of the items relating to section 7 the following:

"(e) Fact sheets.";

(10) by adding at the end of the items relating to section 10 the following:

"(h) Data disclosure to States.
  "(1) In general.
  "(2) Action for just compensation.";

(11) by striking out the item relating to subsections (a) and (b) of section 17 and inserting in lieu thereof the following:

"(a) Pesticides and devices intended for export.
  "(1) Violations.
  "(2) Exports.
  "(3) Notification.
  "(4) Labels.
"(b) Cancellation notices furnished to foreign government.
  "(1) Issuance.
  "(2) Contents.";

(12) by adding at the end of the items relating to section 17 the following:

"(f) Tolerances for agricultural commodities.
  "(1) Registration.
  "(2) Amendment of tolerance.
  "(3) Lowering of tolerance."; and

(13) by adding at the end thereof the following:

"Sec. 32. Employee protection.
  "(a) In general.
  "(b) Administration.".

TITLE XIV—EFFECTIVE DATE

SEC. 1401. EFFECTIVE DATE.

Except as otherwise provided in this Act, this Act and the amendments made by this Act shall become effective 60 days after the date of enactment of this Act.

○

DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20250

June 20, 1986

Honorable Jesse Helms
Chairman, Committee on Agriculture,
Nutrition, and Forestry
United States Senate
Washington, D.C. 20510

Dear Mr. Chairman:

This is in response to your request for a report on S. 2215, a bill "To amend the Federal Insecticide, Fungicide, and Rodenticide Act to ensure safer pesticides and to better protect the public and the environment, and for other purposes."

While we agree with several of the objectives of S. 2215, the Department does not support most of its provisions.

This bill is designed to make major revisions to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and certain provisions would be expected to have significant impact on the cost of production of food, feed and fiber.

The Department is devoted to the maintenance of a safe and wholesome food supply and to the protection of public health. Nevertheless, we believe that the terms of the bill would surface several key problems:

A primary concern is Section 1007 of Title X which would amend section 17 of FIFRA, the portion of the statute which addresses the export of pesticides, by adding a new subsection (f, that requires the revocation or amendment of tolerances (and exemptions from the requirement of a tolerance) and food additive regulations within 60 days of cancellation or other changes in the registration status of a pesticide. Given the statutory context and possible scope of this subsection, we believe that it may be regarded as an effort to restrict imports and, therefore, has the potential for causing our international trading partners to take action to restrict U.S. exports. The mechanism for resolving international issues regarding pesticide residues should continue to be the FAO/WHO Codex Committee on Pesticide Residues of the Codex Alimentarius Commission. Moreover, EPA already has addressed the question of tolerance revocation for cancelled pesticides in a 1982 policy statement with which the Food and Drug Administration (FDA) and, within USDA, the Food Safety and Inspection Service (FSIS) and the Agricultural Marketing Service (AMS) agreed (47 Fed. Reg. 42956, September 29, 1982).

In addition, FIFRA is not the appropriate vehicle to address the subject of these provisions: the tolerances and food additive limitations that are used to regulate the presence of pesticide residues in or on both domestically produced and imported products. EPA's authority to issue, amend, and repeal tolerances in food additive regulations comes from the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 301, 346a, and 348), not FIFRA. It is the FFDCA and USDA statutes incorporating FFDCA requirements that provide the basis for Federal food safety regulation by FSIS and AMS as well as FDA. The issues raised by this subsection clearly are food safety issues, not pesticide registration issues. Therefore, they should be considered in the context of the FFDCA, not FIFRA.

We are also concerned with provisions which could lessen the Department's potential input in certain portions of the review process. First, Section 701 of the bill provides for interim administrative review including review by the EPA Scientific Advisory Panel (SAP). Since the U.S. Department of Agriculture plays a key role in this area, it should be included in this review process. Second, Section 201 of the bill deletes the provisions for concurrence by the Secretary of Agriculture from Section 3(c)(7) dealing with minor use. EPA can always benefit by consulting with the USDA, and we, therefore, recommend that this provision should be retained.

The bill places numerous time constraints upon the EPA. While we defer to EPA on this topic, we feel that many of these time frames are too short to be realistically met. The important thing is for EPA to fully evaluate the scientific data and be afforded the opportunity to make credible decisions. This cannot be done with an arbitrarily short time frame.

Finally, we would comment on Section 302 of the bill which provides for the collection of fees for registration of pesticides. In the main, we would defer to EPA regarding this provision. However, we believe that incentives should be provided for development of minor use pesticides. Further, we believe that the Interregional Project No. 4 dealing with minor use and federal agencies holding pesticide registrations should be granted an exemption from the fee requirement.

The Office of Management and Budget advises that there is no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely,

PETER C. MYERS
Acting Secretary

II

99TH CONGRESS
2D SESSION

S. 2346

To amend the Federal Insecticide, Fungicide, and Rodenticide Act to ensure safer pesticides and to better protect the public and the environment, and for other purposes.

IN THE SENATE OF THE UNITED STATES

APRIL 21, 1986

Mr. HELMS introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

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A BILL

To amend the Federal Insecticide, Fungicide, and Rodenticide Act to ensure safer pesticides and to better protect the public and the environment, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE AND TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Pesticide Reform Act of 1986".

(b) TABLE OF CONTENTS.—The table of contents is as follows:

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SEC. 2. REFERENCES TO THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT.

Except as otherwise specifically provided, whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.).

TITLE I—DEFINITIONS

SEC. 101. CERTIFIED APPLICATOR.

Section 2(e) (7 U.S.C. 136(e)) is amended—

(1) in paragraph (3), by striking out "which is classified for restricted use" and inserting in lieu thereof "for compensation or hire"; and

(2) by adding at the end the following new paragraphs:

"(5) NONCERTIFIED COMMERCIAL APPLICATOR.—Unless otherwise prescribed by the labeling of a pesticide, a pesticide shall be considered to be applied under the direct supervision of a commercial applicator if the pesticide is applied by a person trained and registered under section 4 acting under the instructions and control of a commercial applicator who is available if and when needed, even though such commercial applicator is not physically present at the time and place the pesticide is applied.

"(6) COMPETENT PERSON.—For purposes of paragraph (4), a person shall not be considered 'competent' unless the person—

"(A) has successfully completed the training required under paragraph (7), as verified by the State regulatory authority; and

"(B) is a certified applicator or works under the supervision of a certified applicator.".

SEC. 102. INGREDIENT STATEMENT.

Subsection (n) of section 2 (7 U.S.C. 136(n)) is amended to read as follows:

"(n) INGREDIENT STATEMENT.—

"(1) IN GENERAL.—The term 'ingredient statement' means a statement that contains—

"(A) the name and percentage of each active ingredient, the name of each inert ingredient listed under section 3(h)(1), and the total percentage of all inert ingredients, in the pesticide; and

"(B) if the pesticide contains arsenic in any form, a statement of the percentages of total and water soluble arsenic, calculated as elementary arsenic.

"(2) COMMON NAME.—An inert ingredient listed under section 3(h)(1) shall be identified by its most common name, instead of its chemical name."

SEC. 103. MISBRANDED.

Section 2(q)(1) (7 U.S.C. 136(q)(1)) is amended—

(1) by striking out "or" at the end of subparagraph (G);

(2) by striking out the period at the end of subparagraph (H) and inserting in lieu thereof "; or"; and

(3) by adding at the end thereof the following new subparagraph:

"(I) in the case of a pesticide intended for export that is substantially similar in composition and use pattern to a pesticide registered under section 3, the label does not contain the same health, safety, and hazard precautions as a pesticide registered under section 3, unless such precautions on the label are in conflict with the law of the importing country.".

SEC. 104. PESTICIDE.

Section 2(u) (7 U.S.C. 136(u)) is amended—

(1) by striking out "and" at the end of clause (1); and

(2) by inserting after "desiccant" the following: ", (3) any substance or mixture of substances intended for use as an antimicrobial, and (4) any pesticide product, unless the context otherwise requires".

SEC. 105. STATE.

Section 2(aa) (7 U.S.C. 136(aa)) is amended by adding at the end thereof the following new sentence: "The term 'State' means a State administered as a whole and not a political subdivision of a State.".

SEC. 106. USE OF ANY REGISTERED PESTICIDE IN A MANNER INCONSISTENT WITH ITS LABELING.

The first proviso of section 2(ee) (7 U.S.C. 136(ee)) is amended—

(1) in clause (1), by inserting "rate" after "dosage"; and

(2) by striking out "or (4)" and all that follows through "by the labeling" and inserting in lieu thereof

the following: "(4) mixing a pesticide with a fertilizer or another pesticide if such mixture is not prohibited by the labeling, (5) using a registered pesticide for the formulation of an end use product or repackaging a pesticide that is an end use product, or (6) applying a household cleaning product containing an antimicrobial active ingredient in household or institutional cleaning uses".

SEC. 107. ADDITIONAL DEFINITIONS.

Section 2 (7 U.S.C. 136) is amended by adding at the end the following new subsections:

"(ff) ANTIMICROBIAL.—The term 'antimicrobial' means—

"(1) disinfectants intended to destroy or irreversibly inactivate bacteria, fungi, or viruses on surfaces or inanimate objects;

"(2) sanitizers intended to reduce the number of living bacteria or viable virus particles on inanimate surfaces or in water or air;

"(3) bacteriostats intended to inhibit the growth of bacteria in the presence of moisture;

"(4) sterilizers intended to destroy viruses and all living bacteria, fungi, and their spores on inanimate surfaces;

"(5) fungicides and fungistats intended to inhibit the growth of, or destroy, fungi (including yeasts) on inanimate surfaces; or

"(6) commodity preservatives and protectants intended to inhibit the growth of, or destroy, bacteria in or on raw materials (such as adhesives and plastics) used in manufacturing or manufactured products (such as fuel, textiles, lubricants, wood products, and paints).

"(gg) IMPORTING COUNTRY.—The term 'importing country' means the first country to which a pesticide, device, or active ingredient, subject to the notification requirement of section 17(a), is exported from the United States.

"(hh) LOW VOLUME NONFOOD PESTICIDE USE.—A pesticide use shall be considered a low volume nonfood use if the quantity of potential sales are too small to warrant the cost of complying with a regulation necessary to make such use legal.

"(ii) MATERIAL SAFETY DATA SHEETS.—The term 'material safety data sheet' means a sheet required under section 3(c)(10).

"(jj) OUTSTANDING DATA REQUIREMENT.—

"(1) IN GENERAL.—The term 'outstanding data requirement' means any study, required information, or data necessary to make a determination under section 3(c)(5) that—

"(A) has not been submitted to the Administrator; or

"(B) has been submitted to the Administrator but which the Administrator determines are not valid, complete, or adequate to make a determination under section 3 and the regulations and guidelines issued thereunder.

"(2) FACTORS.—In making a determination under paragraph (1)(B), the Administrator shall examine, at a minimum, relevant protocols, documentation of the conduct and analysis of the study, and the results of the study to determine whether the study and the results of the study fulfill the data requirement for which the study was submitted to the Administrator.

"(kk) PESTICIDE DEALER.—The term 'pesticide dealer' means any person who sells a pesticide to a commercial or private applicator, except that such term shall not include a retail vendor of an antimicrobial or household nonrestricted use pesticide.

"(ll) PESTICIDE PRODUCT.—The term 'pesticide product' means a pesticide in the particular form (including composition, labeling, and packaging) in which the product is (or is proposed to be) distributed or sold.

"(mm) PESTICIDE TESTING FACILITY.—The term 'pesticide testing facility' means any person that conducts any test, study, survey, or investigation of the properties, effects, or behavior of any pesticide (or any ingredient, metabolite, or degradation product thereof) for or on behalf of any registrant, applicant for registration, or other person who sells or distributes the pesticide (or contemplates selling or distributing the pesticide), except that such term does not include any person solely on account of the participation of such person as a cooperator in field testing of a pesticide in compliance with an experimental use permit issued under section 5.

"(nn) POLITICAL SUBDIVISION OF A STATE.—The term 'political subdivision of a State' means any geographical area within a State over which authority is exercised by an elected or appointed official, including a county, township, city, or town.

"(oo) TERMS OF REGISTRATION.—The term 'terms of registration' means the requirements imposed on a pesticide product under this Act concerning the composition, labeling, packaging, and restrictions on the distribution, sale, and use of the product.

"(pp) TO DISTRIBUTE OR SELL.—The term 'to distribute or sell' means to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver, except that such term shall not include the holding or application of a registered pesticide product or use dilution thereof by any applicator who provides a service of controlling pests without delivering any unapplied pesticide to any person so served.".

TITLE II—REGISTRATION OF PESTICIDES

SEC. 201. DATA IN SUPPORT OF REGISTRATION.

Subparagraph (A) of section 3(c)(2) is amended to read as follows:

"(A) DATA IN SUPPORT OF REGISTRATION.—

"(i) The Administrator shall publish guidelines specifying the kinds of information that would usually be required to support the registration of a pesticide and shall revise such guidelines from time to time.

"(ii) If after such publication the Administrator requires any additional kind of information under subparagraph (B), the Administrator shall permit sufficient time for applicants to obtain such additional information.

"(iii) Any Federal agency may proceed with the use of such pesticide unless the Administrator determines that missing or deficient data is sufficiently important to warrant a suspension or cancellation.

"(iv) The Administrator, in establishing guidelines for data requirements for the registration of pesticides with respect to minor uses and with respect to various types and classes of pesticides, shall make such guidelines commensurate with the anticipated extent of use, pattern of use, and the level and degree of potential exposure of man and the environment to the pesticide. In the development of such guidelines, the Administrator shall consider the economic factors of potential national volume of use, extent of distribution, and the impact of the cost of meeting the guidelines on the incentives for any potential registrant to undertake the development of the required data.

"(v) Analyses in support of registration are equivalent to an environmental impact statement and may be incorporated by reference and relied on in any other Federal or cooperative document developed in compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.).

"(vi) Such guidelines may not contain a requirement for applicants to perform human epidemiological studies to obtain or support registrations.

"(vii) Guidelines, and modifications thereof, shall be published in the Federal Register. The Administrator shall provide for public comment for guidance in development of such guidelines or modifications.";

SEC. 202. COMPENSATION FOR DATA ON INERT INGREDIENTS.

Subparagraph (D) of section 3(c)(2) (7 U.S.C. 136a(c)(2)(D)) is amended to read as follows:

"(D) EXEMPTION.—

"(i) No applicant for registration of a pesticide who proposes to purchase a registered pesticide or an inert ingredient from another producer in order to formulate such purchased pesticide or an inert ingredient into an end use product shall be required to—

"(I) submit or cite data pertaining to the safety of such purchased product; or

"(II) offer to pay reasonable compensation otherwise required by paragraph (1)(D) for the use of any such data or reregistration fees.

"(ii) No applicant for registration of a pesticide who proposes to purchase an inert ingredient from another producer in order to formulate the pesticide shall be required to offer to pay reasonable compensation otherwise required by paragraph (1)(D) for a study required to be cited or submitted that was generated pursuant to subsection (h)(7) using authority available to the Administrator."

SEC. 203. TIME FOR ACTING WITH RESPECT TO APPLICATION.

Paragraph (3) of section 3(c) is amended to read as follows:

"(3) TIME FOR ACTING WITH RESPECT TO APPLICATION.—

"(A) The Administrator shall review the application on receipt and provide notification of any deficiencies of content or form within 90 days of receipt.

"(B) If a registrant receives such a notification, the registrant shall provide the additional information or may elect to withdraw the application.

"(C) On review without such notification (or, in the case of a subsequent submission adequate to satisfy a deficiency of information noted by the Administrator, on the receipt of such submission), the Administrator shall act on the application within 180 days of such receipt, unless the Administrator notifies the registrant in writing, specifying the reason for the delay in the registration process.

"(D) If the Administrator fails to act within 360 days of such receipt—

"(i) the application is deemed to be acted on and approved; and

"(ii) the Administrator shall promptly take all actions resulting from such approval under this Act.".

SEC. 204. NOTICE OF APPLICATION.

Section 3(c)(4) (7 U.S.C. 136a(c)(4)) is amended—

(1) in the first sentence, by striking out "promptly" and inserting in lieu thereof "not later than 30 days"; and

(2) in the second sentence, by striking out "30" and inserting in lieu thereof "60".

SEC. 205. APPROVAL OF REGISTRATION FOR SUBSTITUTED INERT INGREDIENTS.

Paragraph (5) of section 3(c) (7 U.S.C. 136a(c)(5)) is amended to read as follows—

"(5) APPROVAL OF REGISTRATION.—

"(A) The Administrator shall register a pesticide if the Administrator determines that, when considered with any restrictions imposed under subsection (d)—

"(i) its composition is such as to warrant the proposed claims for it;

"(ii) its labeling and other material required to be submitted comply with this Act;

"(iii) it will perform its intended function without unreasonable adverse effects on the environment;

"(iv) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment; and

"(v) in the case of an application to amend a registration to substitute an inert ingredient for an inert ingredient listed under subsection (h)(1), that subsection (i)(1) is satisfied.

"(B) The Administrator or any State or State agency shall not make any lack of essentiality a criterion for denying registration of any pesticide.

"(C) If two pesticides meet the requirements of this paragraph, one pesticide shall not be registered in preference to the other pesticide.

"(D) In considering an application for the registration of a pesticide, the Administrator may waive data requirements pertaining to efficacy. If a waiver is granted, the Administrator may register the pesticide without determining that the composition of the pesticide is such as to warrant proposed claims of efficacy.

"(E) If a pesticide is found to be efficacious by any State under section 24(c), a presumption is established that the Administrator shall waive data requirements pertaining to efficacy for use of the pesticide in such State.

"(F) On or after the date specified for submission of a study in subsection (h), an application to register or to amend the registration of an application to register or to amend the registration of a pesticide containing a listed inert ingredient shall be deemed not to satisfy the requirements of this paragraph, unless the application is supported by the study required under paragraph (1)(D).".

SEC. 206. CONDITIONAL REGISTRATION.

Subparagraphs (B) and (C) of section 3(c)(7) (7 U.S.C. 136a(c)(7) (B) and (C)) are amended to read as follows:

"(B)(i) The Administrator may conditionally amend the registration of a pesticide to permit additional uses of such pesticide notwithstanding that data concerning the pesticide may be insufficient to support an unconditional amendment, if the Administrator determines that—

"(I) the applicant has submitted satisfactory data pertaining to the proposed additional use;

"(II) amending the registration in the manner proposed by the applicant would not materially increase the risk of any unreasonable adverse effect on the environment; and

"(III) the additional use is in the public interest.

"(ii) The Administrator or State or State agency shall not make any lack of essentiality a criterion for denying conditional registration of any pesticide.

"(iii) Notwithstanding clause (i), no registration of a pesticide may be amended to permit an additional use of such pesticide if the Administrator has issued a notice stating that such pesticide, or any ingredient thereof, meets or exceeds risk criteria associated in whole or in part with human dietary exposure specified in regulations issued under this Act, and during the pendency of any risk benefit evaluation initiated by such notice, if—

"(I) the additional use of such pesticide involves a major food or feed crop; or

"(II) the additional use of such pesticide involves a minor food or feed crop and the Administrator determines, with the concurrence of the Secretary of Agriculture, that there is available an effective alternative pesticide that does not meet or exceed such risk criteria.

"(iv) An applicant seeking amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under paragraph (5).

"(v) If the applicant is unable to submit an item of data (other than data pertaining to the proposed additional use) because it has not yet been generated, the Administrator may amend the registration of a pesticide under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this Act.

"(vi) If data concerning chronic toxicity (oncogenicity, reproductive effects, and mutagenicity), neurotoxicity, or teratogenicity are required for registration of an additional use of a pesticide that is not a minor use, and such a data requirement was in effect at the time the studies to obtain the data commenced, a conditional registration for such use shall not be granted under this subparagraph unless such data have been submitted.

"(vii) An amendment to an existing conditional registration may be issued if the registrant has initiated necessary tests to secure such data, even though the data have not been submitted.

"(C)(i) Except as provided in clauses (ii) and (iii), the Administrator may conditionally register a pesticide containing an active ingredient not contained in any registered pesticide for a period reasonably sufficient for generation and submission of required data (that are lacking because a period reasonably sufficient for generation of the data has not elapsed since the Administrator first imposed the data requirement) if—

"(I) by the end of such period the Administrator receives such data;

"(II) such data do not meet or exceed the risk criteria specified in regulations issued under this Act; and

"(III) such other conditions as the Administrator may prescribe are met.

"(ii) A conditional registration under this subparagraph shall be granted only if the Administrator determines that—

"(I) use of the pesticide during such period will not cause any unreasonable adverse effect on the environment; and

"(II) use of the pesticide is in the public interest.

"(iii) If data concerning chronic toxicity (oncogenicity, reproductive effects, and mutagenicity), neurotoxicity, or teratogenicity are required for registration of the pesticide that is not a minor use, and such a data requirement was in effect at the time the studies to obtain the data commenced, a conditional registration shall not be granted under this subparagraph unless such data have been submitted.".

SEC. 207. INTERIM ADMINISTRATIVE REVIEW.

(a) Interim Administrative Review.—Paragraph (8) of section 3(c) (7 U.S.C. 136a(c)(8)) is amended to read as follows:

"(8) Interim administrative review.—

"(A)(i) Notwithstanding any other provision of this Act, the Administrator may not initiate a public interim administrative review process to develop a risk-benefit evaluation of the ingredients of a pesticide or any of its uses prior to initiating a formal action to cancel, suspend, or deny registration of such pesticide under this Act, unless such interim administrative process is based on a validated test or other significant evidence raising prudent concerns of an unreasonable adverse risk to man or to the environment.

"(ii) The Administrator shall publish in the Federal Register notice of the definition of the terms 'validated test' and 'other significant evidence' as used in this subparagraph.

"(B)(i) The Administrator may conduct a special review of a pesticide use if the Administrator determines, based on a validated test or other significant evidence, that the use of the pesticide (taking into account the ingredients, impurities, metabolites, and degradation products of the pesticide)—

"(I) may pose a risk of serious acute injury to humans or domestic animals;

"(II) may pose a risk of inducing in humans an oncogenic, heritable genetic, teratogenic, fetotoxic, reproductive effect, or a chronic or delayed toxic effect, which risk is of concern in terms of either the degree of risk to individual humans or the number of humans at some risk, based on effects demonstrated in humans or experimental animals, known or predicted levels of exposure of various groups of humans, and the use of appropriate methods of evaluating data and relating such data to human risk;

"(III) may result in residues in the environment of nontarget organisms at levels that equal or exceed concentrations acutely or chronically toxic to such organisms or at levels that produce adverse reproductive effects in such organisms, as determined on the basis of tests conducted on representative species or from other appropriate data;

"(IV) may pose a risk to the continued existence of any endangered or threatened species designated by the Secretary of the Interior or the Secretary of Commerce under the Endangered Species Act of 1973 (16 U.S.C. 1531 et seq.);

"(V) may result in the destruction or other adverse modification of any habitat designated by the Secretary of the Interior or the Secretary of Commerce under such Act as a critical habitat for any endangered or threatened species; or

"(VI) may otherwise pose a risk to humans or to the environment that is of sufficient magnitude to merit a determination as to whether the use of the pesticide product offers offsetting social, economic, and environmental benefits that justify initial or continued registration.

"(ii) In making a determination that a pesticide use satisfies one of the criteria for issuance of a special review required under clause (i), the Administrator shall consider available evidence concerning both the adverse effect in question and the magnitude and scope of exposure of humans and nontarget organisms associated with use of the pesticide.

"(iii) The Administrator shall—

"(I) provide for preliminary notification of registrants and applicants if the Administrator has determined that the criteria for issuance of a special review may have been met; and

"(II) afford registrants and applicants an opportunity to respond to the notification prior to issuance of a special review.

"(iv)(I) Before initiating an interim administrative review, the Administrator shall notify all registrants, users of the pesticide, and the public of the intent of the Administrator to initiate a public interim administrative review by publishing such notice in the Federal Register.

"(II) The registrants and users of the pesticide shall have 60 days after receipt of the notice in which to respond.

"(III) Within 60 days after the response period, the Administrator shall determine whether an interim administrative review of the pesticide shall be initiated.

"(C)(i) Notice of an interim administrative review shall be provided to all registrants, pesticide users, and interested members of the public and shall be published in the Federal Register.

"(ii) The notice shall state the basis for the review, indicate the availability of all data on which the position of the Administrator is based, and include a request for any additional data needed for the review.

"(iii) Not later than 90 days after publication of a notice of such review, comments may be submitted on such review.

"(iv) Not later than 90 days after the close of the comment period, the Administrator shall review all comments and additional data submitted and shall publish a proposed regulatory position.

"(v) Not later than 45 days after the close of the initial comment period, additional comments may be submitted to the Administrator to address comments filed by other parties.

"(vi)(I) The proposed regulatory position of the Administrator shall be submitted to the Scientific Advisory Panel established under section 25(d) at the next scheduled meeting of the panel for comment solely on relevant scientific issues. Relevant scientific data also may be submitted to the Scientific Advisory Panel concerning such position.

"(II) Not later than 60 days after such meeting, the Scientific Advisory Panel shall issue a report on such position.

"(III) The Administrator shall review and consider the report of the Scientific Advisory Panel.

"(IV) Not later than 60 days after receipt of such report, the Administrator shall issue a final regulatory decision whether to retain. restrict, or cancel the uses of the pesticide.

"(vii) Not later than 2 years after the initiation of a review, the Administrator shall make such decision.

"(viii) The time limits specified in this subparagraph may not be extended, except in exceptional circumstances in which—

"(I) additional data critical to a fair and accurate determination of risks posed by the pesticide are required; and

"(II) the extension is for a period limited to the time required to obtain and review such data on an expedited basis."

(b) APPLICATION OF AMENDMENT.—The amendment made by this section shall apply to interim administrative reviews under section 3(c)(8) initiated after the effective date of this Act.

SEC. 208. PREREGISTRATION ACCESS TO DATA.

Section 3(c) (7 U.S.C. 136a(c)) is amended by adding at the end thereof the following new paragraph:

"(9) PREREGISTRATION ACCESS TO DATA.—

"(A) Prior to the registration of a pesticide, the Administrator shall provide, in accordance with this paragraph, public access to health and safety data that are submitted in support of an initial application for the registration of a new active ingredient or initial food use of a previously registered active ingredient.

"(B) The Administrator shall publish in the Federal Register a notice of such application in accordance with paragraph (4).

"(C) Not later than 30 days after the publication of such notice, to obtain access to the data referred to in subparagraph (A), a person must send by certified mail a request for such access and the affirmation referred to in subparagraph (E) simultaneously to the Administrator and to the applicant for the registration of the pesticide.

"(D) Not later than 15 days after receipt of a request for access to such data and affirmation, the Administrator shall grant or deny such request. The Administrator may not extend the 15-day period for acting on such request.

"(E)(i) Notwithstanding any other provision of law, data referred to in subparagraph (A) may be made available only to a person who provides an affirmation (and such supporting evidence as the Administrator considers necessary) that the person is neither employed by nor acting directly or indirectly on behalf of a person or entity engaged or affiliated with a person engaged in the production, sale, or distribution of a pesticide.

"(ii) For purposes of this subparagraph, an affiliate is a person who directly or indirectly, through one or more intermediates, controls or is controlled by or is under common control with the person specified.

"(iii) The affirmation required under clause (i) shall—

"(I) state that the person is neither employed by nor acting on behalf of any business or entity, or affiliate thereof, engaged in the production, sale, or distribution of a pesticide;

"(II) identify any business, employer, or other entity, if any, on whose behalf the person is requesting access to the data; and

"(III) affirm that the person will not intentionally or recklessly violate this paragraph.

"(iv) Section 1001 of title 18, United States Code, shall apply to an affirmation made under this subparagraph.

"(F)(i) Data relating to a pesticide shall be made available to a person only for the purpose of permitting the person to comment to the Administrator on the application for registration of the pesticide.

"(ii) Except as provided in clauses (iii) and (iv), data obtained under clause (i) may not be—

"(I) published, copied, or transferred to any other individual or entity for use in any manner to obtain approval to sell, manufacture, or distribute a pesticide anywhere in the world; and

"(II) may not be used for any purpose in any court or agency of the United States or any State or political subdivision thereof prior to the decision of the Administrator on the registration of the pesticide or after such decision if the application for registration is denied.

"(iii) Data relating to a pesticide may be reasonably quoted in comments submitted to the Administrator. Such comments may not be made public prior to the decision of the Administrator on the registration of the pesticide or after such decision if the application for registration is denied.

"(iv) Such data and comments may be disclosed consistent with section 10 after registration of the pesticide.

"(G)(i) Data relating to a pesticide may be examined at an office of the Environmental Protection Agency, in accordance with this section, and may not be removed from such office.

"(ii) The Administrator shall maintain a record of the persons who inspect data. A copy of the record entry shall be sent to the data submitter.

"(iii) Once access to the data is granted, the data may be examined and comments on the application shall be filed within 60 days, unless extended an additional 30 days for good cause.

"(iv) If access to the data is denied, comments on the application shall be filed within 60 days from the determination of the Administrator denying access.".

SEC. 209. MATERIAL SAFETY DATA SHEETS.

Section 3(c) (7 U.S.C. 136a(c)) (as amended by section 208 of this Act) is further amended by adding at the end thereof the following new paragraph:

"(10) MATERIAL SAFETY DATA SHEETS.—

"(A) Each pesticide manufacturer or importer shall obtain or develop a material safety data sheet for each pesticide produced or imported. Each affected employee shall have available a material safety data sheet for each pesticide used.

"(B) Each material safety data sheet shall be in English and shall contain at least the following information:

"(i) Except as provided for in clause (vi), the identity used on the label and—

"(I) if the pesticide is a single substance, its chemical and common name;

"(II) if the pesticide is a mixture that has been tested as a whole to determine the hazards of the pesticide, the chemical and common name of the ingredients that contribute to these known hazards, and the common name of the mixture itself; or

"(III) if the pesticide is a mixture that has not been tested as a whole, the chemical and common name of all ingredients that have been determined to be health hazards, and that comprise at least 1 percent of the composition, except that chemicals identified as carcinogens shall be listed in the concentrations that are at least 0.1 percent, and the chemical and common name of all ingredients that have been determined to present a physical hazard when present in the mixture.

"(ii) Physical and chemical characteristics of the hazardous chemical (such as vapor pressure and flash point).

"(iii) The physical hazards of the pesticide, including the potential for fire, explosion, and reactivity.

"(iv) The health hazards of the pesticide, including signs and symptoms of exposure and any medical conditions that are generally recognized as being aggravated by exposure to the chemical.

"(v) The primary route of entry.

"(vi) The permissible exposure limit established by the Secretary of Labor under the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 et seq.), ACGIH Threshold Limit Value, and any other exposure limit used or recommended by the pesticide manufacturer, importer, or employer preparing the material safety data sheet, where available.

"(vii) Whether the pesticide is listed in the National Toxicology Program Annual Report on Carcinogens or has been found to be a potential carcinogen in the International Agency for Research on Cancer Monographs, or by the Secretary of Labor.

"(viii) Any generally applicable precautions for safe handling and use that are known to the pesticide manufacturer, importer, or employer preparing the material safety data sheet, including appropriate hygienic practices, protective measures during repair and maintenance of contaminated equipment, and procedures for clean up of spills and leaks.

"(ix) Any generally applicable control measures that are known to the pesticide manufacturer, importer, or employer preparing the material safety data sheet, such as appropriate engineering controls, work practices, or personal protective equipment.

"(x) Emergency and first aid procedures.

"(xi) The date of preparation of the material safety data sheet or the last change to the sheet.

"(xii) The name, address, and telephone number of the pesticide manufacturer, importer, employer, or other responsible party preparing or distributing the material safety data sheet who can provide additional information on the hazardous chemical and appropriate emergency procedures, if necessary.

"(C) If no relevant information is found for any given category on the material safety data sheet, the pesticide manufacturer, importer, or employer preparing the material safety data sheet shall mark the sheet to indicate that no applicable information was found.

"(D) Where complex mixtures have similar hazards and contents (that is, the pesticide ingredients are essentially the same but the specific composition varies from mixture to mixture) the pesticide manufacturer, importer, or employer may prepare one material safety data sheet to apply to all of these similar mixtures.

"(E) The pesticide manufacturer, importer, or employer preparing the material safety data sheet shall ensure that the information recorded accurately reflects the scientific evidence used in making the hazard determination. If the pesticide manufacturer, importer, or employer becomes newly aware of any significant information regarding the hazards of a pesticide, or ways to protect against the hazards, this new information shall be added to the material safety data sheet within 3 months. If the pesticide is not currently being produced or imported, the pesticide manufacturers or importer shall add the information to the material safety data sheet before the chemical is introduced into the workplace again.

"(F) Pesticide manufacturers or importers shall ensure that distributors and manufacturing purchasers of pesticides are provided an appropriate material safety data sheet with the initial shipment, and with the first shipment after a material safety data sheet is updated. The pesticide manufacturer or importer shall either provide material safety data sheets with the shipped containers or send them to the manufacturing purchaser prior to or at the time of the shipment. If the material safety data sheet is not provided with the shipment, the manufacturing purchaser shall obtain one from the pesticide manufacturer, importer, or distributor as soon as possible.

"(G) Distributors shall ensure that material safety data sheets, and updated information, are provided to other distributors and manufacturing purchasers of hazardous chemicals.

"(H) Each employer shall maintain copies or the required material safety data sheets for each pesticide in the workplace and shall ensure that the sheets are readily accessible during each work shift to employees when the employees are in their work area.

"(I) Material safety data sheets may be kept in any form, including operating procedures, and may be designed to cover groups of pesticides in a work area where it may be more appropriate to address the hazards of a process rather than individual pesticides, except that each employer shall ensure that the required information is provided for each pesticide and is readily accessible during each work shift to employees when the employees are in their work area.

"(J) On approval of the registration of a pesticide, a material safety data sheet shall be maintained and kept current by the registrant and made available to the public by the State or designated State agency and the registrants upon request.

"(K) Within 120 days of the effective date of the Pesticide Reform Act of 1986, each registrant or producer of a currently registered pesticide active ingredient or pesticide containing an inert ingredient listed under subsection (h)(1) shall submit a material safety data sheet to the appropriate State or designated State agency.

"(L) Such material safety data sheets shall be—

"(i) maintained and kept current by the registrants; and

"(ii) made available to the public by the State or designated State agency and the registrants on request.

"(M) The State or designated State agency may provide this information to the public, including but not limited to local police, fire, and health authorities, local officials, pesticide users, pesticide applicators, persons at manufacturing and use localities, and other members of the public.

"(N) On approval of the registration of a pesticide, a list of locations where the pesticide active ingredient will be produced in the United States shall be—

"(i) maintained and kept current by the registrant; and

"(ii) made available to the public by the State or designated agency and the registrants on request."

SEC. 210. CLASSIFICATION FOR RESTRICTED USE.

Subparagaph (C) of section 3(d)(1) (7 U.S.C. 136a(d)(1)(C)) is amended to read as follows:

"(C) The Administrator shall classify a pesticide, or the particular use or uses to which the determination applies, for restricted use if the Administrator determines that—

"(i) the pesticide when applied in accordance with—

"(I) its directions for use, warnings, and cautions for the uses for which it is registered or for one or more of such uses; or

"(II) widespread and commonly recognized practices,

may generally cause unreasonable adverse effects on the environment, including injury to the applicator; and

"(ii) such unreasonable adverse effects cannot be adequately addressed by revised or additional warnings and directions for use in the labeling or other regulatory restrictions.".

SEC. 211. REREGISTRATION OF PESTICIDES.

Subsection (g) of section 3 (7 U.S.C. 136a(g)) is amended to read as follows:

"(g) REREGISTRATION OF PESTICIDES.—

"(1) IN GENERAL.—The Administrator shall reregister each pesticide in accordance with this subsection.

"(2) LISTS OF PESTICIDE ACTIVE INGREDIENTS.—

"(A) Not later than 90 days after the effective date of the Pesticide Reform Act of 1986, the Administrator shall publish in the Federal Register a list of 300 pesticide active ingredients not reregistered since September 30, 1978, in the order of their priority, for reregistration under this Act.

"(B) Not later than 180 days after the effective date of the Pesticide Reform Act of 1986, the Administrator shall publish in the Federal Register a list of all pesticide active ingredients remaining after subparagraph (A) that have not been reregistered since September 30, 1978, in the order of their priority, for reregistration under this Act.

"(3) PRIORITY.—In establishing the lists required under paragraph (2), the Administrator shall give the highest priority to pesticides that—

"(A) are in use on or in food or feed;

"(B) will result in detectable residues of verifiable toxicological concern in potable ground water, edible fish, or shellfish; or

"(C) have previously been determined by the Administrator to have the most significant outstanding data requirements.

"(4) REMOVAL.—Not later than 90 days after the publication of a list containing an active ingredient of a pesticide under paragraph (2), the Administrator shall remove such ingredient from the reregistration list if the Administrator is requested by each registrant of each pesticide containing such ingredient that the registration of such pesticide be canceled. Prior to such cancellation, the Administrator shall publish in the Federal Register a notice of intent to cancel to allow public comment within 60 days of the notice.

"(5) NOTIFICATION.—For each pesticide active ingredient listed pursuant to paragraphs (2)(A) and (2)(B), the registrant shall provide written notification to the Administrator of the intent of the registrant to seek reregistration of the pesticide active ingredient. If the registrant or interested parties fails to respond to the Federal Register notice published under paragraph (2)(A) or (2)(B) within 180 days of such notice, the Administrator may issue a notice of intent to cancel such registration and allow 60 days for public comment on the notice.

"(6) JUDICIAL REVIEW.—The establishment of a list by the Administrator under this subsection shall not be subject to judicial review.

"(7) DATA REQUIREMENTS.—

"(A)(i) For each pesticide active ingredient listed in the notice required pursuant to paragraph (2)(A), the Administrator shall request that the registrant submit a list of all outstanding data requirements within 180 days of such notice in the Federal Register.

"(ii) Not later than the end of the 12th, 24th, and 36th month following the effective date of the Pesticide Reform Act of 1986, the Administrator shall—

"(I) identify and publish in the Federal Register a list of all outstanding data requirements based on the priorities of the Administrator; and

"(II) simultaneously notify existing registrants of each pesticide active ingredient pursuant to subsection (c)(2)(B) that, in order to maintain the registration of such pesticide under this Act, such registrants must complete studies to fill such outstanding data requirements within a reasonable time, but not to exceed 4 years, after such notice.

"(iii) The Administrator may extend the period by no more than 3 years if extraordinary circumstances beyond the control of the registrant prevent submission of necessary studies, including nonnegligent loss o laboratory results, destruction of laboratory, unavailability of laboratory facilities, major animal loss, or similar unanticipated catastrophes.

"(B)(i) For each pesticide active ingredient listed in the notice required pursuant to paragraph (2)(B), the Administrator shall request that the registrant submit a list of all outstanding data requirements within 180 days of such notice in the Federal Register.

"(ii) Not later than the end of the 36th month following the effective date of the Pesticide Reform Act of 1986, the Administrator shall—

"(I) identify and publish in the Federal Register a list of all outstanding data requirements; and

"(II) simultaneously notify existing registrants of each pesticide active ingredient pursuant to subsection (c)(2)(B) that, in order to maintain the registration of such pesticide under this Act, such registrants must complete studies to fill such outstanding data requirements within a reasonable time, but not to exceed 4 years, after such notice.

"(iii) The Administrator may extend the period by no more than 3 years if extraordinary circumstances beyond the control of the registrant prevent submission of necessary studies, including nonnegligent loss of laboratory results, destruction of laboratory, unavailability of laboratory facilities, major animal loss, or similar unanticipated catastrophes.

"(iv) If a registrant fails to comply with the requirements of subsection (c)(2)(B) within the required times, the Administrator shall issue a notice of intent to suspend such registration pursuant to subsection (c)(2)(B)(iv).

"(v) If a hearing is requested following such a suspension notice, the registrant may appeal in such hearing whether the Administrator properly classified a study as an outstanding data requirement and other matters identified for resolution in such subsection.

"(8) FILLING DATA REQUIREMENTS.—

"(A) Not later than 6 months after issuance of a notice required under paragraph (7) with respect to a pesticide active ingredient, the Administrator shall determine whether appropriate tests have been committed or contracted to fill the identified outstanding data requirements for such pesticide active ingredient.

"(B) A registrant shall submit annual progress reports to the Administrator that indicate the status of such testing and report interim results.

"(9) SUSPENSION.—

"(A) The Administrator shall provide written notice to a registrant of findings under this subparagraph and allow the registrant to respond within 60 days if the Administrator determines that—

"(i) important tests essential to a determination of whether or not the pesticide may cause unreasonable adverse effects on the environment have not been committed or contracted for within 1 year of the notice required under paragraph (7);

"(ii) progress is insufficient to ensure completion of such tests within the deadlines established in such notice; or

"(iii) the required test data have not been submitted within the specified deadline.

"(B) Within 30 days of receiving the written comments of a registrant, the Administrator may immediately issue a notice of intent to suspend such registration pursuant to subsection (c)(2)(B)(iv).

"(10) REREGISTRATION.—

"(A) Not later than 2 years after receipt of the data required by this subsection with respect to a pesticide, the Administrator shall complete reregistration of such pesticide by determining whether such pesticide fulfills the requirements of subsection (c)(5). In extraordinary circumstances, the Administrator may extend the limit prescribed by this subparagraph after notifying Congress and publishing such notice in the Federal Register at least 60 days prior to the required deadline.

"(B) Reregistration shall be accomplished by a thorough examination of all health and safety data required by the regulations and guidelines issued pursuant to section 3 or taking other action necessary to make such determination.

"(11) COMPENSATION.—

"(A) On submission of data as required under this subsection, the data submitter shall be entitled to be compensated pursuant to subsection (c)(1)(D).

"(B) If there are two or more registrants for an active ingredient registered under this Act, the compensation shall be apportioned on the basis of the market share of a registrant.

"(12) LACK OF ESSENTIALITY.—The Administrator shall not make any lack of essentiality a criterion for denying the reregistration of any pesticide.".

SEC. 212. PRIORITY LIST FOR INERT INGREDIENTS.

Section 3 (7 U.S.C. 136a) is amended by adding at the end thereof the following new subsection:

"(h) PRIORITY LIST FOR INERT INGREDIENTS.—

"(1) ESTABLISHMENT.—

"(A) The Administrator shall establish a priority list of not more than 50 inert ingredients consisting of—

"(i) inert ingredients that appear to cause a pesticide to meet or exceed a criterion for initiating an interim administrative review established under subsection (c)(8); and

"(ii) inert ingredients for which additional data are reasonably necessary to evaluate whether the inert ingredient may result in a pesticide causing an unreasonable adverse effect on the environment—

"(I) that are similar in molecular structure to a chemical that is oncogenic, mutagenic, teratogenic, or causes another significant adverse effect; and

"(II) from which a significant hazard may exist from use in pesticides and exposure to the pesticide containing the inert ingredient, based on a risk assessment.

"(B) In establishing the priority list, the Administrator shall take into account—

"(i) the differences in concept, usage, and environmental risk between various classes of pesticides; and

"(ii) data for evaluating such risk between agricultural and nonagricultural pesticides.

"(C) The Administrator shall not place on the priority list inert ingredients that are incidental contaminants formed during the production process and that are inextricably linked to the technical grade product.

"(2) PUBLICATION OF LIST.—Not later than 90 days after the effective date of the Pesticide Reform Act of 1986, the Administrator shall publish the priority list required under paragraph (1). The Administrator shall publish revisions to such list at least annually.

"(3) JUDICIAL REVIEW.—The priority list and any revisions to the priority list shall be subject to judicial review under section 16 at the time an initial or revised priority list is published.

"(4) REMOVAL OF INGREDIENTS INVOLVING ADMINISTRATIVE REVIEWS.—An inert ingredient listed on the priority list pursuant to paragraph (1)(A)(i) shall be removed from the priority list on—

"(A) a final decision by the Administrator not to initiate an interim administrative review with respect to any pesticide containing the inert ingredient, or final action by the Administrator concluding interim administrative review, and all actions under section 6 resulting therefrom; or

"(B) a final decision by the Administrator under paragraph (6)(E) not to require additional data to be generated, or the receipt and evaluation by the Administrator of all data required to be submitted under paragraph (6), and all actions under section 6 resulting therefrom.

"(5) REMOVAL OF INGREDIENTS INVOLVING ADDITIONAL DATA.—An inert ingredient listed on the priority list pursuant to paragraph (1)(A)(ii) shall be removed from the priority list on—

"(A) a final decision by the Administrator under paragraph (6)(E) not to require additional data to be generated; or

"(B) the receipt and evaluation by the Administrator of all data required to be generated under this subsection and all actions under section 6 resulting therefrom.

"(6) ADDITIONAL DATA.—

"(A) For each inert ingredient in an end use pesticide listed pursuant to paragraph (1), if the Administrator determines that additional data are required under subsection (c)(2)(A), the Administrator shall provide notice of such requirement to all registrants of an end use pesticide containing inert ingredient under subsection (c)(2)(B) and producers of the inert ingredient.

"(B) If the Administrator determines that additional data are required, the Administrator shall consider the following:

"(i) A discussion of the risks and benefits raised by the inert ingredient in the pesticide, the anticipated exposures to man and the environment from the use of the ingredient in pesticides, and the reasoning supporting the need for further testing.

"(ii) In the case of an inert ingredient listed under paragraph (1)(A)(i), the studies that the Administrator proposes to require to address the concerns identified pursuant to clause (i), or, if the Administrator proposes not to require additional studies, a discussion of the reasons for not requiring any additional studies.

"(iii) In the case of an inert ingredient listed under paragraph (1)(A)(ii), the studies that the Administrator proposes to require to address the concerns identified pursuant to clause (i) or, if the Administrator proposes not to require additional studies, a discussion of the reasons for not requiring any additional studies.

"(iv) The regulatory mechanisms or other procedures the Administrator proposes to use to generate the studies.

"(v) The dates for submission of the studies, which shall provide for submission of the studies within a reasonable time, not to exceed 5 years from the promulgation of the final notice under subsection (c)(2). The Administrator may extend this period by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent submission of necessary studies.

"(C) In preparing a requirement for additional data under subsection (c)(2)(B), the Administrator shall consider—

"(i) the minor use factors specified in subsection (c)(2)(A);

"(ii) the guidelines published pursuant to subsection (c)(2)(A);

"(iii) the use of a tiered testing program, under which the need for long-term studies would be evaluated after receipt of short-term studies;

"(iv) the use of other statutory authorities of the Administrator to require the generation of the identified studies considering nonpesticide uses; and

"(v) data generated or scheduled for generation.

"(D) The Administrator shall allow 90 days for the registrants, inert ingredient producers, pesticide users, and the public to comment on the data requirements.

"(E)(i) Within 180 days after notification, the Administrator shall publish a list of data requirements or make a final decision to require no additional data or studies.

"(ii) The list of data requirements and label requirements shall be subject to judicial review under section 16 at the time of publication. The omission of an inert ingredient from the priority list established under paragraph (1) shall not be subject to judicial review under section 16.

"(iii) If a hearing is requested by a registrant, the registrant may contest whether the Administrator properly considered the factors described in subparagraphs (B) and (C).

"(F) On receipt of the additional data for each inert ingredient submitted pursuant to subparagraph (E), the Administrator shall, within 2 years, evaluate the data and take such steps as are appropriate to prevent unreasonable adverse effects on the environment of pesticides containing such inert ingredient, unless additional time is needed.

"(G) Any study submitted under subsection (c)(2)(B) that was conducted with funds that are not public funds, using another statutory authority of the Administrator, shall be treated, for purposes of subsection (c)(1)(D), as having been submitted in support of registration. The person who submitted the study shall be treated as an original data submitter."

SEC. 213. SUBSTITUTION OF INERT INGREDIENTS.

Section 3 (7 U.S.C. 136a) (as amended by section 212 of this Act) is further amended by adding at the end thereof the following new subsection:

"(i) SUBSTITUTION OF INERT INGREDIENTS.—The Administrator shall approve an application to amend the registration of a pesticide to substitute an inert ingredient for an inert ingredient listed under subsection (h)(1), if the Administrator finds, on the basis of similarity in molecular structure to a chemical known to cause significant adverse effects, existing data, or such short-term tests as the Administrator determines are necessary, that the substitute inert ingredient does not pose the same or similar concerns about unreasonable adverse effects on the environment that resulted in the listing of the listed inert ingredient.".

SEC. 214. LABELING OF INERT INGREDIENTS.

Section 3 (7 U.S.C. 136a) (as amended by section 213 of this Act) is further amended by adding at the end thereof the following new subsection:

"(j) LABELING OF INERT INGREDIENTS.—

"(1) AMENDED LABEL.—

"(A) A risk assessment, based on data required under subsection (c)(2) and other authority of the Administrator, shall be performed to determine whether an end use pesticide presents a potential significant hazard from the use of the inert ingredient in question.

"(B) If the risk assessment shows that a significant hazard may result from the use of the inert ingredient in question, the registrant of end use pesticides containing the listed ingredient, at a level that presents the hazard, shall apply, within 90 days of publication of such hazard finding in the Federal Register, for amended registration to change the label of the pesticide to conform with sections 2(n), 2(p), and 2(q).

"(C) Risk assessments shall be subject to review by a scientific review panel to be established by the Administrator for such purpose.

"(2) MISBRANDING.—A pesticide, the ingredient statement of which does not satisfy section 2(n) with respect to a listed inert ingredient, shall not be considered misbranded until a date of manufacture that is 360 days after the publication of the risk assessment indicating a significant hazard may exist for the pesticide containing the inert ingredient, or the date on which the Administrator approves a registration amendment providing for a change in the label of the pesticide to satisfy section 2(n), whichever occurs later.".

SEC. 215. FORMULA STATEMENTS.

Section 3 (7 U.S.C. 136a) (as amended by section 214 of this Act) is further amended by adding at the end thereof the following new subsection:

"(k) FORMULA STATEMENTS.—

"(1) LISTED INERT INGREDIENTS.—Within 120 days of the initial publication of the risk assessment conclusions pursuant to subsection (j)(1), each registrant of a pesticide containing such inert ingredient or ingredients that contributes to a significant hazard from use of the end use pesticide shall make any necessary modifications to the formula statement submitted pursuant to subsection 3(c)(1)(E) to satisfy the requirements of the Administrator with respect to such ingredient or ingredients.

"(2) ALL INERT INGREDIENTS.—Within 240 days of the initial publication of the risk assessment conclusions pursuant to subsection (j)(1), each registrant of a pesticide containing such inert ingredient or ingredients shall apply for amended registration, to make any necessary modifications to the formula statement submitted pursuant to subsection (c)(1)(E) to satisfy the requirements of the Administrator with respect to such ingredient or ingredients."

TITLE III—CERTIFIED APPLICATORS

SEC. 301. STATE CERTIFICATION.

Section 4(a)(2)(B) (7 U.S.C. 136b(a)(2)(B)) is amended by inserting after "plan" the following: ", including requirements for State enforcement personnel to be certified in the restricted and nonrestricted use pesticide application categories for which the personnel are assigned enforcement responsibility".

SEC. 302. APPLICATOR TRAINING.

Section 4 (7 U.S.C. 136b) is amended by adding at the end thereof the following new subsections:

"(d) COMMERCIAL APPLICATOR CERTIFICATION.—

"(1) CRITERIA.—Notwithstanding subsection (a), in order to be certified as a commercial applicator, an applicant must, at a minimum—

"(A) have undergone training prescribed and administered by the Administrator and the delegate State agency (including training with the use of updated national core material issued within 9 months after the effective date of the Pesticide Reform Act of 1986) on the use of appropriate application and safety procedures, clothing, and protective equipment, the detection of common symptoms of pesticide poisoning, the means of obtaining emergency medical treatment, and the requirements of laws, regulations, and labeling (including training in hazards posed by pesticides to workers, the public health, and the environment) that is conducted by trainers whose minimum competency requirements and range of expertise shall be prescribed by the Administrator or the delegate State agency; and

"(B) have field or industrial plant experience in pesticide use and application.

"(2) EXPERIENCE.--The Administrator or the State lead agency shall establish the specific category of use and related minimum length of experience commensurate with potential risks and exposure to the applicator and the environment, except that such minimum length of service requirement may not exceed 2 years.

"(3) ADDITIONAL TEST.—To receive certification as a commercial applicator, an applicant must, in addition to the requirements of paragraph (1), pass (with at least 70 percent correct) an exam prescribed by the State delegate agency, including topics addressed in the national core material training.

"(e) NONCERTIFIED COMMERCIAL APPLICATOR TRAINING AND REGISTRATION.—To operate as a noncertified commercial applicator working under the direct supervision of a commercial applicator, a person must—

"(1) have undergone basic training prescribed and administered by the Administrator or the delegate State agency (including training with the use of updated national core material issued within 12 months after the effective date of the Pesticide Reform Act of 1986) on the use of appropriate application and safety procedures, clothing, and protective equipment, the detection of common symptoms of pesticide poisoning, the means of obtaining emergency medical treatment, and the requirements of laws, regulations, and labeling (including training in hazards posed by pesticides to workers, the public health, and the environment) that is conducted by trainers whose competency requirements and range of expertise shall be prescribed by the Administrator or the State lead agency; and

"(2) register with the delegate State agency responsible for certifying pesticide applicators by providing to the State agency a signed statement from the trainer and operator stating that the prescribed minimum training standards have been provided to the applicant and received by the operator.

"(f) CERTIFIED AND NONCERTIFIED PRIVATE APPLICATOR TRAINING.—To qualify as a certified or noncertified private applicator, other than as an applicator of antimicrobial or nonrestricted use pesticides to their own or rented property, an applicant must, at a minimum—

"(1) have undergone training based on updated national core material and conducted by trainers whose minimum competency requirement and range of expertise are prescribed by the State lead agency; and

"(2) register with the delegate State agency as required by subsection (e)(2).

"(g) RETRAINING AND RECERTIFICATION.—All applicators, certified or noncertified, must—

"(1) undergo retraining (to be prescribed by the delegate State agency in accordance with updated national core material) on an ongoing basis over a 5-year period; and

"(2) be reaffirmed at the end of the period based on compliance with competency requirements established for each category of applicator in this section.

"(h) UNIFORM TRAINING.—A person shall be considered to have satisfied this section if the person has completed a uniform nationwide course of training for workers that is approved by the Administrator, applies to more than one State, issues credentials to workers on completion, and is subject to verification.

"(i) TRAINING FOR PESTICIDE APPLICATORS AND TRAINERS.—

"(1) IN GENERAL.—The Administrator, in consultation with interested States, shall prescribe minimum requirements for training programs for pesticide applicators and application trainers.

"(2) STATE PROGRAM.—The Administrator shall delegate authority to prescribe and administer a training program under this subsection to any State that has established a program that meets such requirements.

"(3) PRIVATE PROGRAM.—The Administrator or delegate State agency shall approve any privately administered training program under this subsection that the Administrator determines meets such requirements.

"(j) WORKER TRAINING.—Each employee who mixes, loads, or applies a pesticide shall be required to receive training in—

"(1) safety and application procedures to be followed;

"(2) worker, public health, and environmental hazards involved;

"(3) clothing and protective equipment to be used;

"(4) common symptoms of pesticide poisoning;

"(5) the location of emergency medical treatment; and

"(6) applicable laws, regulations, and label requirements pertaining to the pesticide uses.".

TITLE IV—ADMINISTRATIVE REVIEW; SUSPENSION

SEC. 401. PUBLIC HEARINGS AND SCIENTIFIC REVIEW.

The tenth sentence of section 6(d) (7 U.S.C. 136d(d)) is amended by striking out "90 days thereafter" and inserting in lieu thereof "18 months after issuance of the notice that gave rise to the hearing, or such shorter time specified in subsection (e)(2),".

SEC. 402. CANCELLATION OF REGISTRATION BASED ON FALSE OR INVALID DATA.

Section 6 (7 U.S.C. 136d) is amended by adding at the end thereof the following new subsection:

"(g) CANCELLATION OF REGISTRATION BASED ON FALSE OR INVALID DATA.—

"(1) PREVIOUSLY DETERMINED INVALID DATA.—

"(A) The Administrator shall immediately issue a notice of intent to suspend and to cancel the registration of a pesticide if—

"(i) prior to the effective date of the Pesticide Reform Act of 1986, the Administrator has previously determined that data submitted by a registrant to the Administrator in support of an existing registration were invalid;

"(ii) the data have not been replaced; and

"(iii) the data are important data essential to the determination of the Administrator of whether or not the pesticide may cause unreasonable adverse effects to the environment.

"(B) The Administrator shall not issue a notice of intent to suspend and to cancel the registration of a pesticide if the Administrator and registrant have agreed on a plan for replacement studies under paragraph (2).

"(2) NEW INVALID DATA.—

"(A) If, after the effective date of the Pesticide Reform Act of 1986, the Administrator determines that invalid data have been submitted by a registrant to the Administrator in support of a registration of a pesticide, the Administrator may require either the active ingredient registrant or end use pesticide registrant to submit replacement studies or data on an expedited schedule and with interim progress reports.

"(B) The Administrator shall permit pesticide users to submit replacement studies or data on an expedited schedule and with interim progress reports.

"(C) If no commitment to submit replacement studies or data is forthcoming and the Administrator determines that such action would be in the public interest, taking into account the scope of the invalid data, the Administrator may issue a notice of intent to cancel such registration.

"(3) FALSE DATA.—If a registrant willfully submits material data known to be false in support of the registration of a pesticide, the Administrator shall immediately issue a notice of intent to suspend and cancel such registration.

"(4) HEARING.—

"(A) Any suspension or cancellation under this subsection shall become final and effective at the end of the 30-day period beginning on receipt by the registrant of a notice issued under this section unless during such period a request for a hearing is made by a person adversely affected.

"(B) A hearing under this paragraph shall be conducted in accordance with subparagraph (C), (D), or (E), as appropriate.

"(C) The only matters for resolution at a hearing conducted with respect to action taken under paragraph (1) shall be whether—

"(i) in response to a notice of the Administrator issued under section 3(c)(2)(B) or other formal notice, data previously determined by the Administrator to be invalid—

"(I) have not been replaced by the registrant on the effective date of the Pesticide Reform Act of 1986; or

"(II) are in the process of being replaced on the effective date of such Act but have not been submitted to the Administrator; and

"(ii) the data are important to the registration.

"(D) The only matters for resolution at a hearing conducted with respect to action taken under paragraph (2) shall be whether data are invalid, important, and necessary to adequately determine whether a pesticide may cause unreasonable adverse effects on the environment.

"(E) The only matters for resolution at a hearing conducted with respect to action taken under paragraph (3) shall be whether a registrant willfully submitted important data known to be false.

"(F) A decision after completion of a hearing conducted under this paragraph shall be final.

"(G) Notwithstanding any other provision of this Act, a hearing shall be held, and a determination made, under this subsection within 75 days after the receipt of a request for such hearing.".

SEC. 403. COMPENSATION FOR DATA.

Section 6 (7 U.S.C. 136d) (as amended by section 402 of this Act) is further amended by adding at the end the following new subsection:

"(h) COMPENSATION FOR DATA.—On submission of data as required under this section, the data submitter shall be entitled to be compensated in accordance with section 3(c)(1)(D).".

SEC. 404. VOLUNTARY CANCELLATION.

Section 6 (7 U.S.C. 136d) (as amended by section 403 of this Act) is further amended by adding at the end thereof the following new subsection:

"(i) VOLUNTARY CANCELLATION.—

"(1) REQUESTS.—A registrant may at any time request that any of the product registrations of the registration be canceled or be amended to delete one or more uses.

"(2) NOTICE.—Prior to such cancellation, the Administrator shall publish in the Federal Register a notice of intent to cancel and allow public comment within 60 days of notice.

"(3) CANCELLATION.—The Administrator shall approve such a request unless—

"(A) the product is the subject of a cancellation proceeding under section 6; and

"(B) the Administrator determines that the public interest would be served by disapproving the request and continuing such cancellation proceeding."

TITLE V—REGISTRATION OF ESTABLISHMENTS

SEC. 501. CONFIDENTIAL RECORDS AND INFORMATION.

Section 7(d) (7 U.S.C. 136e(d)) is amended by inserting "and production locations" after "names".

SEC. 502. MATERIAL SAFETY DATA SHEETS.

Section 7 (7 U.S.C. 136e) is amended by adding at the end the following:

"(e) MATERIAL SAFETY DATA SHEETS.—Any producer operating a registered establishment shall obtain and make available to the public, on request, a material safety data sheet developed under section 3(c)(10) for each active ingredient and listed inert ingredient used in the establishment.".

SEC. 503. CONFIDENTIALITY.

Section 7 (7 U.S.C. 136e) (as amended by section 502 of this Act) is further amended by adding at the end thereof the following new subsection:

"(f) CONFIDENTIALITY.—Other than the name of a pesticide or active ingredient used in producing a pesticide or active ingredient used in producing a pesticide produced, sold or distributed at an establishment, any information submitted to the Administrator, State, or designated State agency pursuant to subsection (c) shall be considered confidential and subject to section 10.".

SEC. 504. INFORMATION REQUESTED.

Section 7 (7 U.S.C. 136e) (as amended by section 503 of this Act) is further amended by adding at the end the following:

"(g) INFORMATION REQUESTED.—Consistent with section 3507(a)(1) of title 44, United States Code, the Administrator shall make efforts to catalog and retrieve data in a manner that eliminates or reduces additional information requests from registrants, particularly requests that require the submission of duplicate confidential data.".

TITLE VI—BOOKS AND RECORDS

SEC. 601. BOOKS AND RECORDS.

The first sentence of section 8(a) (7 U.S.C. 136f(a)) is amended by inserting ", exporters, and pesticide testing facilities" after "producers".

TITLE VII—INSPECTION OF ESTABLISHMENTS

SEC. 701. AUTHORITY TO ENTER, INSPECT, AND COPY.

Subsection (a) of section 9 (7 U.S.C. 136g(a)) is amended to read as follows:

"(a) AUTHORITY TO ENTER, INSPECT, AND COPY.—An officer or employee of the United States or of any State, designated by the Administrator, is authorized at reasonable times, as provided by this section—

"(1) to enter any place where any pesticide, active ingredient, or device is distributed or sold, in order to inspect and obtain samples of any pesticide, active ingredient, or device being distributed or sold at such place or of any packaging or labeling of any such pesticide, active ingredient, or device;

"(2) to enter any place where there are located any records required by or under this Act, or any place reported pursuant to section 8(a) as a location where such records are maintained, in order to inspect and obtain copies of such records;

"(3) to enter any pesticide testing facility, in order—

"(A) to inspect the facility and the testing being conducted at the facility; and

"(B) to inspect and obtain copies of any records required by or under the authority of this Act to be maintained by the pesticide testing facility; and

"(4) to enter any place where such officer or employee has probable cause to believe that the Act has been or is being violated by any person other than a person acting in the capacity of a private applicator, in order to inspect such place to obtain evidence of such violation.".

SEC. 702. WARRANTS.

Subsection (b) of section 9 (7 U.S.C. 136g(b)) is amended to read as follows:

"(b) WARRANTS.—An officer or employee of the United States or of any State, designated by the Administrator, is empowered to obtain and to execute warrants authorizing—

"(1) entry for the purposes of this section;

"(2) inspection and copying of all records required under this Act; and

"(3) seizure of any pesticide or device that is in violation of this Act.".

SEC. 703. PROCEDURE.

Section 9 (7 U.S.C. 136g) is amended by adding at the end the following new subsection:

"(d) PROCEDURE.—

"(1) CREDENTIALS AND STATEMENTS.—Before any entry or inspection of any premises not open to the general public is made under this section, the person conducting the inspection shall present to the person in charge of the premises appropriate credentials and a written statement of the reason for the inspection and whether a violation of the law is suspected.

"(2) Promptness.—Each inspection shall be commenced and completed with reasonable promptness.

"(3) Samples.—If the person conducting the inspection obtains any samples of pesticides or devices, prior to leaving the premises, the inspector shall give to the person in charge of the premises a receipt describing the samples and, if requested and practicable, a portion of each such sample equal in volume or weight to the portion retained. If an analysis of any such sample is made, a copy of the results of such analysis shall be furnished to the person in charge of the premises.".

SEC. 704. COORDINATION.

Section 9 (7 U.S.C. 136g) (as amended by section 703 of this Act) is further amended by adding at the end the following new subsection:

"(e) Coordination.—The Administrator shall coordinate actions taken under this section with actions taken under other Federal laws, including the Toxic Substances Control Act (15 U.S.C. 2601 et seq.), Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), and the Resource Conservation and Recovery Act of 1976 (42 U.S.C. 6901 et seq.), for the purpose of avoiding duplication of inspections.".

TITLE VIII—PROTECTION OF TRADE SECRETS AND OTHER INFORMATION

SEC. 801. DISCLOSURE OF INERT INGREDIENTS PERMITTED.

Section 10(d)(1)(C) (7 U.S.C. 136h(d)(1)(C)) is amended by inserting before the period the following: ", except that the identity of an inert ingredient listed under section 3(h)(1) shall be disclosed in accordance with paragraph (4)".

SEC. 802. DISCLOSURE OF INTENT TO MARKET PESTICIDES.

Section 10(d)(1) (7 U.S.C. 136h(d)(1)) is amended—

(1) by striking out "or" at the end of subparagraph (B);

(2) by striking out the period at the end of subparagraph (C) and inserting in lieu thereof ", or"; and

(3) by adding at the end thereof the following new subparagraph:

"(D) discloses any information regarding an intent to market a pesticide prior to the start of sales of the pesticide, unless such disclosure is necessary to protect against a suspected unreasonable risk to health or the environment.".

SEC. 803. METHODS OF DISCLOSING INERT INGREDIENTS.

Section 10(d) (7 U.S.C. 136h(d)) is amended by adding at the end thereof the following new paragraph:

"(4)(A) The identity of an inert ingredient may be disclosed by means of—

"(i) the listing of the ingredient on the priority list required by section 3(h)(1); or

"(ii) release of product labels disclosing the identity of an inert ingredient on the priority list.

"(B) The Administrator may continue to require identification of an inert ingredient on a product label pursuant to section 2(n) after the removal of the ingredient from the priority list pursuant to paragraph (4) or (5) of section 3(h) if the Administrator has issued a notice under section 3(c)(6) or (8)."

SEC. 804. DELAY IN PUBLIC NOTIFICATION.

Section 10(d) (7 U.S.C. 136h(d)) (as amended by section 803 of this Act) is further amended by adding at the end the following new paragraph:

"(5)(A) If a registrant demonstrates a future intention to market a registered product and the intention is not a matter of public record, the Administrator may grant a delay in public notification of a registered label, and documents relating to such registration, until the first date of the commercial disclosure of the product by or on behalf of the registrant.

"(B) The registrant shall provide adequate notice in advance of the commercial disclosure of the product so that the Administrator may thereafter disclose the available data subject to this section.

"(C) This paragraph shall not limit the ability of the Administrator to disclose such information if the Administrator determines that disclosure is necessary to protect against an unreasonable adverse effect on health or the environment.".

SEC. 805. DATA DISCLOSURE TO CONTRACTORS.

Subsection (e) of section 10 (7 U.S.C. 136h(e)) is amended to read as follows:

"(e) DISCLOSURE TO CONTRACTORS.—

"(1) Information otherwise protected from disclosure to the public in subsection (b) may be disclosed to a contractor with the United States, a State or State agency, or an employee of the contractor, under such conditions as the Administrator may specify, if, in the opinion of the Administrator, such disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States or a State or State agency for the performance of work in connection with this Act.

"(2) The Administrator shall require as a condition of the disclosure of information under this subsection that the person receiving the information take such security precautions respecting the information as the Administrator shall by regulation prescribe.".

SEC. 806. DATA DISCLOSURE TO STATES.

Section 10 (7 U.S.C. 136h) is amended by adding at the end thereof the following new subsection:

"(h) DATA DISCLOSURE TO STATES.—

"(1) Notwithstanding any limitation contained in this section or any other provision of law, information reported to or otherwise obtained by the Administrator under this Act shall be made available to any State or State agency that enters into a cooperative agreement with the Administrator in accordance with this subsection.

"(2) At any time, the Governor of a State or the duly authorized head of a State agency may submit a written request to enter into a cooperative agreement with the Administrator for access to specified information obtained under this Act. Such request shall include—

"(A) a description of the types of information for which access is sought;

"(B) an explanation of how the availability of such information relates to protection of health and the environment; and

"(C) proof that no laws or regulations of the State require disclosure of the data to any person, organization, or entity who would not be entitled to obtain the data from the Administrator under this Act.

"(3)(A) Within 90 days of receiving the request, the Administrator shall grant the request if the Administrator determines that the requestor has complied with paragraph (2).

"(B) A denial of a request by the Administrator shall include a written explanation stating the specific reasons for such denial.

"(C) On the granting of a request and the execution or modification of an agreement, the Administrator shall publish a notice in the Federal Register identifying the requestor and the nature of the information sought.

"(D) The agreement shall become effective 30 days after publication in the Federal Register.

"(4)(A) A cooperative agreement under this subsection may be in effect for up to 3 years.

"(B) Not less than 90 days before the expiration of an agreement, a requestor seeking renewal of an agreement shall provide a written certification that reaffirms that the requestor has complied with paragraph (2).

"(C) If a requestor acts in a timely manner, the agreement shall remain in effect until the Administrator renews the agreement.

"(D) Not less than 90 days before the expiration of an agreement, a requestor seeking modification of an agreement must comply with paragraph (2) to modify the agreement.

"(E) The Administrator shall act on a request for modification in accordance with paragraph (3).

"(5)(A)(i) Any current or former officer or employee of the United States or any State or State agency who—

"(I) by virtue of such employment or official position has obtained possession of, or has access to, material the disclosure of which is prohibited by this subsection;

"(II) knowing that disclosure of such material is prohibited by this subsection, willfully discloses the material in any manner to any person not entitled to receive such material; and

"(III) solicits such disclosure or obtains such material knowing that the release is unlawful,

shall be guilty of a misdemeanor and fined not more than $25,000 or imprisoned for not more than 1 year, or both.

"(ii) Section 1905 of title 18, United States Code, shall not apply with respect to the publishing, divulging, disclosure, or making known, or making available, information reported or otherwise obtained under this subsection.

"(B) For purposes of this paragraph—

"(i) any contractor with the United States or State or State agencies who is furnished information as authorized by subsection (a)(2), and any employee of any such contractor, shall be considered to be an employee of the United States; and

"(ii) any employee or any contractor or any employee of any such contractor of any State or State agency who is furnished information under a cooperative agreement with the Administrator, shall be considered to be an employee of the United States.".

SEC. 807. NOTICE OF REQUEST FOR DATA DISCLOSURE.

Section 10 (7 U.S.C. 136h) (as amended by section 806 of this Act) is further amended by adding at the end thereof the following new subsection:

"(i) NOTICE.—If the Administrator receives a request for data required or submitted under this Act, the Administrator shall provide the data submitter with notice of the request within 7 working days after receipt of the request.".

TITLE IX—STANDARDS APPLICABLE TO PESTICIDE APPLICATORS

SEC. 901. STANDARDS APPLICABLE TO PESTICIDE APPLICATORS.

Section 11 (7 U.S.C. 136i) is amended by adding at the end thereof the following new subsections:

"(c) Records of Commercial Applicators.—

"(1) Pesticide applications.—A commercial applicator shall maintain a record of each pesticide application, including the identity and amount of the pesticides applied and the date and location of the application.

"(2) Duration.—A commercial applicator shall maintain a record required under this subsection for a period of 2 years after the application.

"(d) Records of Pesticide Dealers.—

"(1) Pesticide sales.—A pesticide dealer shall maintain a record of each pesticide sale, other than the sale of an antimicrobial or nonrestricted use pesticide, to a private or commercial applicator. Such record shall include the identity of the pesticide, to whom the pesticide was distributed or sold, the date of the distribution or sale, and the amount of distribution or sale.

"(2) DURATION.—A pesticide dealer shall maintain the records required under this subsection for a period of 3 years after the sale.

"(e) INSPECTION OF RECORDS.—For purposes of enforcing this Act, on request of the Administrator or an officer or employee of a State, a commercial applicator and a pesticide dealer shall furnish or permit the Administrator, officer, or employee at all reasonable times to have access to, and to copy, records maintained in accordance with subsections (c) and (d).

"(f) ACCESS TO RECORDS.—

"(1) IN GENERAL.—The records required to be kept under subsections (c) and (d) shall be accessible within 30 days after an application or sale.

"(2) CONFIDENTIAL BUSINESS INFORMATION.—Information obtained that identifies the location of application sites, customers, types of pesticides used or sold, amounts used or sold, dates and locations of sales, or other information that may provide a competitive advantage if disclosed shall be considered confidential business information under this Act.

"(3) EMPLOYEE ACCESS.—An employee shall have access to information records maintained under this section that directly relate to the employment duties of the employee.

"(4) CUSTOMER ACCESS.—A customer shall have access to information records maintained under this section that directly relate to pesticide applications for which the customer has contracted.".

TITLE X—UNLAWFUL ACTS

SEC. 1001. DISTRIBUTION OR SALE OF CERTAIN PESTICIDES.

Section 12(a)(1) (7 U.S.C. 136j(a)(1)) is amended—

(1) in the matter preceding clause (A), by striking out "distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver or offer to deliver, to any person" and inserting in lieu thereof "to distribute or sell to any person"; and

(2) by striking out clause (A) and inserting in lieu thereof the following new clause:

"(A) any pesticide product that is not registered under section 3 or whose registration has been canceled or suspended, except to the extent that distribution or sale otherwise has been authorized by the Administrator under this Act;".

SEC. 1002. OTHER UNLAWFUL ACTS.

Section 12(a)(2) (7 U.S.C. 136j(a)(2)) is amended—

(1) by striking out clause (B) and inserting in lieu thereof the following new clause:

"(B) to refuse to—

"(i) prepare, maintain, or submit any records required under this Act;

"(ii) submit any reports required by this Act; or

"(iii) allow any inspection, copying of records, or sampling authorized by this Act;";

(2) in clause (F), by striking out "to make" and inserting in lieu thereof "to distribute, sell, or make";

(3) in clause (J), by striking out "section 6" and inserting in lieu thereof "this Act";

(4) by striking out clause (K) and inserting in lieu thereof the following new clause:

"(K) to violate any cancellation order issued under this Act;";

(5) in clause (M), by striking out "section 8" and inserting in lieu thereof "this Act";

(6) by striking out "or" at the end of clause (O);

(7) by striking out the period at the end of clause (P) and inserting in lieu thereof a semicolon; and

(8) by adding at the end thereof the following new clauses:

"(Q) to willfully falsify all or part of any data submitted pursuant to this Act, or to willfully submit such false data knowing it to be false;

"(R) to violate any regulation prescribed by the Administrator to carry out good laboratory practice standards;

"(S) to distribute or sell, to make available for use, or to use any pesticide product that is the subject of an exemption under section 18 in violation of the terms of the exemption;

"(T) who is a registrant, an applicant for registration, or a pesticide testing facility, to falsify or misrepresent any information relating to the testing of any pesticide (or any ingredient, metabolite, or degradation product thereof), including the nature of any protocol, procedure, substance, organism, or equipment used, observation made, or conclusion, or opinion formed if such representation is made to the Administration, or is made in any document or record that the person making the representation knows will be furnished to the Administrator or will become a part of any records required to be maintained under this Act;

"(U) who is a registrant, an applicant for registration, a pesticide testing facility, a distributor or seller of any pesticide, a commercial applicator, or a hired applicator of any pesticide, to violate any regulation issued under this Act; or

"(V) to apply a pesticide as a commercial or private applicator, certified or uncertified, without receiving training required under this Act.".

SEC. 1003. LIABILITY FOR PESTICIDE USE DAMAGE.

Section 12 (7 U.S.C. 136j) is amended by adding at the end thereof the following new subsection:

"(c) LIABILITY FOR PESTICIDE USE DAMAGE.—

"(1) IN GENERAL.—Notwithstanding any other provision of law, an agricultural producer or applicator shall not be liable in any action brought under this Act or for damages caused by pesticide use unless the producer or applicator acted unreasonably with regard to such pesticide use or application.

"(2) LABEL APPLICATION.—Proof that a pesticide application was made in accordance with the label of the pesticide shall be presumptive evidence that the applicator acted reasonably.".

SEC. 1004. ACTS OF AGENTS.

Section 12 (7 U.S.C. 136j) (as amended by section 1003 of this Act) is further amended by adding at the end the following:

"(d) ACTS OF AGENTS.—When construing and enforcing this Act, the act, omission, or failure of any officer, employee, agent, or other person acting for or employed by any person shall be considered the act, omission, or failure of such person as well as that of the person employed.".

TITLE XI—PENALTIES

SEC. 1101. CIVIL PENALTIES.

Section 14(a) (7 U.S.C. 136l(a)) is amended—

(1) in paragraph (1)—

(A) by inserting after "commercial applicator," the following: "applicant for restricted use pesticide registration, pesticide testing facility,";

(B) by striking out "distributor" and inserting in lieu thereof "person who distributes or sells any pesticide or device";

(C) by striking out "$5,000" and inserting in lieu thereof "$10,000"; and

(D) by adding at the end thereof "For purposes of this subsection, each day after citation for such a violation that a pesticide registrant or distributor continues to commit such a violation shall constitute a separate offense.";

(2) in paragraph (2)—

(A) by striking out "$1,000" each place it appears and inserting in lieu thereof "$2,000"; and

(B) by striking out "$500" and inserting in lieu thereof "$1,000";

(3) in paragraph (3), by adding at the end thereof the following new sentence: "If the person neither resides nor has a principal place of business in the United States, the Administrator may designate a site for the hearing in the United States that is reasonably convenient for the parties."; and

(4) in the first sentence of paragraph (4), by inserting "any economic benefit resulting from the violation," after "to continue in business,".

SEC. 1102. CRIMINAL PENALTIES.

Section 14(b) (7 U.S.C. 136l(b)) is amended—

(1) in paragraph (1)—

(A) by inserting after "commercial applicator," the following: "applicant for restricted use pesticide registration, pesticide testing facility,";

(B) by striking out "distributor" and inserting in lieu thereof "person who distributes or sells any pesticide or device,"; and

(C) by striking out "one year" and inserting in lieu thereof "2 years";

(2) in paragraph (2)—

(A) by striking out "$1,000" and inserting in lieu thereof "$2,000"; and

(B) by striking out "30 days" and inserting in lieu thereof "1 year";

(3) by striking out paragraph (3) and inserting in lieu thereof the following new paragraph:

"(3) DISCLOSURE OF INFORMATION.—

"(A) Any person who uses or reveals information relative to the formula of a product acquired under section 3, shall be fined not more than $25,000 or imprisoned for not more than 3 years, or both.

"(B) Any person, including any officer, contractor, contractor employee, or employee of the United States or a State or State agency who—

"(i) is granted access to data under section 3(c)(9) or 10; and

"(ii) in furtherance of a commercial purpose involving the production, registration, distribution, or sale of a pesticide—

"(I) knowingly violates such section; or

"(II) knowingly allows data to be made available in violation of such section,

shall be fined not more than $100,000 or imprisoned for not more than 3 years, or both."; and

(4) by striking out paragraph (4).

SEC. 1103. SUBPOENAS.

Section 14 (7 U.S.C. 136l) is amended by adding at the end thereof the following new subsection:

"(c) SUBPOENAS.—

"(1) ISSUANCE.—The Administrator may—

"(A) in connection with an administrative proceeding under subsection (a), issue a subpoena to compel the attendance and testimony of a witness or a subpoena duces tecum; and

"(B) request the Attorney General to bring an action to enforce any subpoena issued under this subsection.

"(2) JURISDICTION.—A district court of the United States shall have jurisdiction to enforce such subpoena and impose a sanction.".

TITLE XII—ADMINISTRATIVE PROCEDURE; JUDICIAL REVIEW

SEC. 1201. REVIEW OF REGULATIONS.

Section 16 (7 U.S.C. 136n) is amended by adding at the end thereof the following new subsection:

"(e) REVIEW OF REGULATIONS.—

"(1) IN GENERAL.—Any regulation issued under this Act and first published in the Federal Register in final form after the effective date of the Pesticide Reform Act of 1986, or any refusal to modify or rescind such a regulation, shall be reviewable only as provided by this subsection.

"(2) COURT.—Any person may obtain judicial review of such a regulation or refusal by filing a petition for review in the United States court of appeals for the circuit in which the person resides or has its principal place of business or in the United States Court of Appeals for the District of Columbia.

"(3) REVIEW OF ISSUED REGULATIONS.—Any petition under this subsection for review of a regulation shall be filed within 90 days from the date of promulgation of the regulation as determined by the Administrator in the Federal Register.

"(4) REVIEW OF REFUSAL TO MODIFY OR RESCIND.—Any petition under this subsection for review of a refusal to modify or rescind a regulation shall be filed within 90 days after such refusal.

"(5) SCOPE OF REVIEW.—The scope of review shall be as specified in section 706 of title 5, United States Code.

"(6) STAYS.—The commencement of proceedings under this paragraph shall not, unless specifically ordered by the court to the contrary, operate as a stay of the regulation.

"(7) JUDICIAL REVIEW.—Action of the Administrator with respect to which review could have been obtained under this subsection shall not be subject to judicial review in any suspension, cancellation, or denial proceeding under this Act, or any appeal therefrom, nor in any proceeding under section 13, 14, or 16(c) or any appeal therefrom.".

TITLE XIII—IMPORTS AND EXPORTS

SEC. 1301. PESTICIDES AND DEVICES INTENDED FOR EXPORT.

(a) IN GENERAL.—Subsection (a) of section 17 (7 U.S.C. 136o(a)) is amended to read as follows:

"(a) PESTICIDES AND DEVICES INTENDED FOR EXPORT.—

"(1) VIOLATIONS.—Notwithstanding any other provision of this Act, no pesticide or device or active ingredient used in producing a pesticide intended solely for export to any foreign country shall be considered in violation of this Act when prepared or packed according to the specifications or directions of the foreign purchaser, except that producers of such pesticides and devices and active ingredients used in producing pesticides shall be subject to sections 2(p), subparagraphs (A), (C), (D), (E), (G), (H), and (I) of section 2(q)(1), subparagraphs (A), (B), (C)(i), (C)(iii), and (D) of section 2(q)(2), sections 7 and 8, and paragraphs (2), (3), (4), (5), and (6) of section 17(a).

"(2) Exports.—

"(A) This paragraph applies to a pesticide, device, or active ingredient—

"(i) for which a restricted use classification has become effective under section 3;

"(ii) for which a cancellation or suspension has become effective under section 6;

"(iii) the registration of which has been voluntarily withdrawn by the registrant, if such withdrawal was associated with concern over potential adverse public health or environmental effects; or

"(iv) that is not registered under section 3 for any use.

"(B) No pesticide, device, or active ingredient described in subparagraph (A) may be exported to any foreign country by any person unless, at least 30 days prior to the first shipment each year of such pesticide to such country, such person has—

"(i) notified, pursuant to paragraph (3), the person importing the pesticide and the appropriate government regulatory office in the importing country;

"(ii) received written evidence that the notification was delivered to the appropriate government regulatory office; and

"(iii) submitted a copy of the notification in English and evidence of delivery to the Administrator.

"(C) Documents referred to in subparagraph (B) shall be made available to the public, on request.

"(3) NOTIFICATION.—The notification required pursuant to paragraph (2) shall be made in an appropriate language and shall contain the following information:

"(A) The name of the pesticide and the common and chemical names of the active ingredient.

"(B) The name and address of the person exporting the pesticide.

"(C) The name and address of the person importing the pesticide.

"(D) The name and address of the appropriate government regulatory office in the importing country.

"(E) A statement of the reasons why the pesticide was canceled, suspended, voluntarily withdrawn, is not registered in the United States, or has been classified for restricted use, and the list of restrictions.

"(F) The name and address of the office of the United States Environmental Protection Agency that, on request by the importer or official of the importing country, can provide additional information on the pesticide.

"(4) LABELS.—

"(A) The label of pesticides intended for export from the United States shall be written in an appropriate language.

"(B) Except as provided in section 2(q)(1)(H), such label may not refer to compliance with the laws of the United States unless the label also contains or is accompanied by a description of the relevant requirements of such laws.".

(b) EFFECTIVE DATES.—

(1) Paragraphs (2) and (3) of section 17(a) (as amended by subsection (a) of this section) shall become effective 90 days after the date of enactment of this Act.

(2) Not later than 30 days after the date of enactment of this Act, the Administrator of the Environmental Protection Agency shall publish in the Federal Register a list of the names, addresses, and international telecommunications codes of appropriate regulatory offices required to receive notices under section 17(a)(2)(B).

(3) Not later than 180 days after the date of enactment of this Act, and annually thereafter, the Administrator shall revise the list required under paragraph (2).

(4) Not later than 90 days after the date of enactment of this Act, the Administrator shall publish in the Federal Register preliminary guidelines regarding—

(A) the form of the notification required under section 17(a)(2);

(B) translation of the notification and labels required under such section into the appropriate language;

(C) retention of shipping documents and other pertinent records by exporters under such section; and

(D) procedures for public access to documents submitted by exporters under such section.

(5) Not later than 1 year after the date of enactment of this Act, the Administrator shall issue such regulations as are necessary to carry out section 17(a) (2) and (3) and this subsection.

SEC. 1302. CANCELLATION NOTICES FURNISHED TO FOREIGN GOVERNMENTS.

Subsection (b) of section 17 (7 U.S.C. 136o(b)) is amended to read as follows:

"(b) CANCELLATION NOTICES FURNISHED TO FOREIGN GOVERNMENT.—

"(1) ISSUANCE.—If a registration, or a cancellation or suspension of the registration, of a pesticide becomes effective, or ceases to be effective, or a pesticide is classified for restricted use, the Administrator shall transmit through the State Department notification thereof to the governments of other countries and to appropriate international agencies.

"(2) CONTENTS.—Such notification shall, on request, include the reasons for the cancellation, suspension, or restriction and information concerning other pesticides that are registered under section 3 and that could be used in lieu of such pesticide.".

SEC. 1303. COOPERATION IN INTERNATIONAL EFFORTS.

Subsection (d) of section 17 (7 U.S.C. 136o(d)) is amended to read as follows:

"(d) COOPERATION IN INTERNATIONAL EFFORTS.—The Administrator shall—

"(1) in cooperation with the Department of State, other appropriate Federal agencies, and nongovernmental and international organizations, actively participate in international efforts to develop improved pesticide research; and

"(2) report to Congress annually on the activities conducted to comply with this subsection and the results thereof.".

TITLE XIV—RESEARCH AND MONITORING

SEC. 1401. RESEARCH.

Subsection (a) of section 20 (7 U.S.C. 136r(a)) is amended to read as follows:

"(a) RESEARCH.—

"(1) IN GENERAL.—The Administrator shall undertake such research as may be necessary to carry out this Act, including research by grant or contract with other Federal agencies, universities, or other entities or persons.

"(2) INTEGRATED PEST MANAGEMENT.—The Administrator shall conduct research into integrated pest management in cooperation with the Secretary of Agriculture.

"(3) DUPLICATION.—The Administrator shall ensure that research conducted under this subsection does not duplicate research being undertaken by any other Federal agency. Such agency may not be required to duplicate or supplement research already reviewed and accepted by the Administrator in the course of registration and the finding of no unreasonable adverse impact resulting from the use of registered material.".

TITLE XV—DELEGATION AND COOPERATION

SEC. 1501. EFFECT ON CERTAIN OTHER LAWS.

Section 22 (7 U.S.C. 136t) is amended by adding at the end the following new subsection:

"(c) EFFECT ON CERTAIN OTHER LAWS.—

"(1) IN GENERAL.—In exercising any authority under this Act, the Administrator shall not, for the purposes of section 4(b)(1) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653(b)(1)), be considered to be exercising statutory authority to prescribe or enforce standards or regulations affecting occupational safety or health.

"(2) COORDINATION.—The Administrator and the Secretary of Labor shall coordinate efforts to regulate pesticide use in the workplace so as to minimize burdens on regulated persons.".

TITLE XVI—STATE COOPERATION, AID, AND TRAINING

SEC. 1601. AUTHORIZATION FOR APPROPRIATIONS.

(a) IN GENERAL.—Section 23 (7 U.S.C. 136u) is amended—

(1) in subsection (a), by striking out the second and third sentences; and

(2) by adding at the end thereof the following new subsection:

"(d) AUTHORIZATION FOR APPROPRIATIONS.—

"(1) CERTIFIED APPLICATOR TRAINING.—

"(A) There are authorized to be appropriated for the fiscal year ending September 30, 1987, and each fiscal year thereafter, such sums as may be necessary for the Administrator to provide through cooperative agreements an amount equal to 50 percent of the anticipated cost to each State or Indian tribe, as agreed to under cooperative agreements, of conducting training programs for certification of applicators during such fiscal year.

"(B) Funds shall be distributed among States and Indian tribes on a formula basis, as determined by the Secretary of Agriculture and the Administrator.

"(2) PESTICIDE CERTIFICATION AND LICENSING PROGRAMS.—

"(A) There are authorized to be appropriated for the fiscal year ending September 30, 1987, and each fiscal year thereafter, such sums as may be necessary—

"(i) for the Administrator to provide through cooperative agreements an amount equal to 50 percent of the anticipated cost to each State or Indian tribe, as agreed to under cooperative agreements, of conducting pesticide certification and licensing programs during such fiscal year; and

"(ii) in the case of a State, for administering the State plan of each State approved under section 4(a)(2).

"(B) Funds shall be distributed among the States and Indian tribes on a formula basis as determined by the Administrator.

"(3) APPROPRIATED AMOUNTS.—

"(A) The total amount authorized to be appropriated under paragraphs (1) and (2) may not be less than $5,000,000 for each fiscal year.

"(B) If funds sufficient to pay 50 percent of the costs under paragraphs (1) and (2) for any year are not appropriated, the share of each State or Indian tribe shall be reduced in a like proportion in allocating available funds.

"(4) COORDINATION.—States conducting training and certification programs under State plans shall coordinate such programs to assure that standards for certification of applicators of pesticides are attained and maintained and prescribed by the Administrator under section 4.".

(b) EFFECTIVE DATE.—The amendments made by this section shall become effective October 1, 1986.

TITLE XVII—AUTHORITY OF STATES

SEC. 1701. PESTICIDE SALE OR USE.

(a) IN GENERAL.—Subsection (a) of section 24 (7 U.S.C. 136v(a)) is amended to read as follows:

"(a) Sale or Use.—A State, but not a political subdivision of a State, may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent that the regulation does not permit any sale or use prohibited by this Act, except that—

"(1) a State shall not make any lack of essentiality a criterion for regulating the sale or use of a pesticide; and

"(2) a State shall not establish any tolerance for a pesticide residue that is different from, or in addition to, a tolerance for the residue established under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)."

(b) Clerical Amendment.—Section 24(b) is amended by inserting after the subsection designation the following: "Labeling or Packaging.—".

SEC. 1702. ADDITIONAL USES.

(a) In General.—Section 24(c) (7 U.S.C. 136c(v)) is amended by striking out "(c) and all that follows through the end of paragraph (1) and inserting in lieu thereof the following:

"(c) Additional Uses.—

"(1) Special local needs.—

"(A) In addition to regulating the sale or use of federally registered pesticides pursuant to subsection (a), a State may provide registration for additional uses of federally registered pesticides formulated for distribution and use within the State to meet special local needs.

"(B) Such registration shall be considered registration under section 3 for all purposes under this Act, but shall authorize distribution and use only within such State.

"(C) Such registration shall terminate, without further action by the Administrator, on the earlier of—

"(i) the end of any period established by the State for the registration of the use; or

"(ii) 10 days after the date the Administrator publishes in the Federal Register a notice stating that the State that issued the registration has informed the Administrator that the State no longer desires the registration to continue in effect.".

(b) CLERICAL AMENDMENTS.—Section 24(c) is amended—

(1) by making the margins for paragraphs (2) through (4) the same as the margin for paragraph (1) (as amended by subsection (a));

(2) in paragraph (2), by inserting "DISAPPROVAL.—" after the paragraph designation;

(3) in paragraph (3), by inserting "TOLERANCES OR EXEMPTIONS.—" after the paragraph designation; and

(4) in paragraph (4), by inserting "CONTROLS.—" after the paragraph designation.

SEC. 1703. DIFFERENCES IN USAGE AND RISK.

Section 24 (7 U.S.C. 136v) is amended by adding at the end the following new subsection:

"(d) DIFFERENCES IN USAGE AND RISK.—In promulgating any regulations, policies, or protocols pertaining to the sale or use of pesticides within a State, the State shall take into account the difference in concept and usage between various classes of pesticides and the differences in environmental risk and the appropriate data for evaluating such risk between agricultural and nonagricultural pesticides.".

SEC. 1704. LOW VOLUME NONFOOD PESTICIDE USE.

Section 24 (7 U.S.C. 136v) (as amended by section 1703 of this Act) is further amended by adding at the end the following new subsection:

"(e) LOW VOLUME NONFOOD PESTICIDE USE.—

"(1) IN GENERAL.—

"(A) Any person may petition the Administrator to conduct a rule making on the record after an opportunity for a hearing in accordance with subchapter II of chapter 5 of title 5, United States Code, to amend requirements, regulations, or policies established under this Act governing low volume nonfood pesticide uses.

"(B) The Administrator shall publish notice of the petition in the Federal Register, and conduct a rule making, on a showing by the petitioner that the potential market for the low volume nonfood pesticide use in question is too small to warrant the cost of complying with the regulation.

"(2) INFORMAL RULE MAKING.—Notwithstanding paragraph (1), the Administrator may conduct rule making under paragraph (1) in accordance with the first two sentences of section 553 of title 5, United States Code.

"(3) CRITERIA.—

"(A) The criteria for granting or denying a request of a petitioner shall be whether or not the proposed amendment will cause an unreasonable risk to man or the environment.

"(B) The Administrator and the petitioner, in consultation with other interested parties, may establish an innovative solution to the problems raised in a petition filed under this subsection (including the amendment or exemption from certain requirements or policies) that is consistent with subparagraph (A).

"(4) DURATION.—Unless specified as part of the outcome of the rule making, an amendment to a low volume nonfood use granted under this subsection shall terminate after 2 years. After such termination, the petitioner may repetition the Administrator in accordance with this subsection.

"(5) DESCRIPTION.—

"(A) If the Administrator decides that an amended use may be permitted under this subsection, the Administrator shall publish a notice of the decision in the Federal Register.

"(B) The Administrator shall prepare a one-page description of the amended use and provide notice of the availability of the description in the notice published under subparagraph (A).

"(C) To maintain an amended use under this subsection, the applicator must make available the description and post a copy of the description at the site of each application of the amended use.".

TITLE XVIII—AUTHORITY OF ADMINISTRATOR

SEC. 1801. CONGRESSIONAL REVIEW OF RULES AND REGULATIONS.

Section 25(a)(4) (7 U.S.C. 136w(a)(4)) is amended—

(1) in the second sentence of subparagraph (A)—

(A) by striking out "both Houses of Congress adopt a concurrent resolution" and inserting in lieu thereof "a joint resolution is enacted";

(B) by striking out "That Congress disapproves the" and inserting in lieu thereof "The"; and

(C) by inserting "is disapproved" before the closed quotation marks; and

(2) in the first sentence of subparagraph (B), by striking out "concurrent resolution" and inserting in lieu thereof "joint resolution".

SEC. 1802. SCIENTIFIC ADVISORY PANEL.

Section 25(d) (7 U.S.C. 136w(d)) is amended—

(1) in the first sentence, by striking out "The" and inserting in lieu thereof "Except when a referral is made pursuant to an interim administrative review in section 3(c)(8)(C) to the Scientific Advisory Panel established by this subsection, the"; and

(2) in the eighteenth sentence, by striking out "1987" and inserting in lieu thereof "1991".

TITLE XIX—STATE PRIMARY ENFORCEMENT RESPONSIBILITY

SEC. 1901. STATE PRIMARY ENFORCEMENT RESPONSIBILITY.

(a) In General.—Subsection (a) of section 26 (7 U.S.C. 136w-1(a)) is amended to read as follows:

"(a) State Responsibility.—

"(1) Criteria.—For purposes of this Act, a State shall have primary enforcement responsibility for pesticide use violations during any period for which the Administrator determines that such State—

"(A) has adopted adequate pesticide use laws and regulations, except that the Administrator may not require a State to have pesticide use laws that are more stringent than this Act;

"(B) has adopted and is implementing adequate procedures for the enforcement of such State laws and regulations;

"(C) will keep records necessary to provide an annual programmatic review showing compliance with clauses (A) and (B);

"(D) will report emergency conditions to the Administrator at the earliest practical date.

"(2) Coordination.—For purposes of this section, the term 'primary enforcement responsibility' shall include primary enforcement responsibility over an action that has been proposed by a State and approved by the Administrator, including the banning, seizure and cancellation of a registered product. The Administrator and the State shall coordinate actions affecting registered products.".

(b) CLERICAL AMENDMENTS.—Section 26 is amended—

(1) in subsection (b), by inserting "STATE PLANS.—" after the subsection designation; and

(2) in subsection (c), by striking out "the" after the subsection designation and inserting in lieu thereof "ADMINISTRATOR RESPONSIBILITY.—The".

SEC. 1902. CERTIFICATION IN PESTICIDE USE APPLICATIONS.

Section 26 (7 U.S.C. 136w–1) is amended by adding at the end the following new subsection:

"(d) CERTIFICATION IN PESTICIDE USE APPLICATIONS.—To enforce requirements of this Act with respect to restricted and nonrestricted use pesticide applications, a employee of the Environmental Protection Agency must be certified in the State for the category of such applications for which the employee is assigned enforcement responsibility.".

SEC. 1903. POLITICAL SUBDIVISIONS.

Section 26 (7 U.S.C. 136w–1) (as amended by section 1902 of this Act) is amended by adding at the end the following new subsection:

"(e) POLITICAL SUBDIVISIONS.—This section does not extend enforcement authority or responsibility to any political subdivision of a State."

TITLE XX—FAILURE BY THE STATE TO ASSURE ENFORCEMENT OF STATE PESTICIDE USE REGULATIONS

SEC. 2001. STATE ENFORCEMENT ACTIONS.

(a) IN GENERAL.—Subsection (a) of section 27 (7 U.S.C. 136w–2) is amended to read as follows:

"(a) COMPLAINTS.—

"(1) REFERRAL.—On receipt of any complaint or other information alleging or indicating a significant violation of the pesticide use provisions of this Act, the Administrator shall refer the matter to the appropriate State officials for investigation of the matter consistent with this Act.

"(2) INVESTIGATION.—As soon as practicable after a complaint is filed and in no event later than 30 days after the filing of the complaint, the State shall commence appropriate investigative action.

"(3) ACTION BY ADMINISTRATOR.—If the State has not commenced appropriate enforcement action within 120 days of the filing of the complaint, the Administrator may act on the complaint or information to the extent authorized under this Act.".

(b) CLERICAL AMENDMENTS.—Section 27 is amended—

(1) in subsection (b), by inserting "RESCISSION.—" after the subsection designation; and

(2) in subsection (c), by inserting "EMERGENCIES.—" after the subsection designation.

TITLE XXI—DATA COLLECTION AND RETRIEVAL SYSTEMS

SEC. 2101. DATA COLLECTION AND RETRIEVAL SYSTEMS.

The Act is amended—

(1) by redesignating section 31 (7 U.S.C. 136y) as section 32; and

(2) by inserting after section 30 the following new section:

"SEC. 31. DATA COLLECTION AND RETRIEVAL SYSTEMS.

"(a) DATA COLLECTION SYSTEM.—

"(1) IN GENERAL.—In consultation with a committee established by the Administrator within the Environmental Protection Agency, the Administrator shall design and implement an efficient system within the Agency for the collection, dissemination (to other Federal and State departments and agencies), and use of data submitted to the Administrator under this Act.

"(2) ADVISORY COMMITTEE.—The Administrator and the committee established under paragraph (1) shall solicit advice from data users outside the Federal Government by means of an advisory committee that shall consist of representatives from private groups, State governments and organizations, industry, and other appropriate representatives.

"(b) DATA RETRIEVAL SYSTEM.—

"(1) IN GENERAL.—In consultation and cooperation with the Secretary of Agriculture and the heads of other appropriate Federal and State departments and agencies design, the Administrator shall design and implement an efficient and effective system for the retrieval of pesticidal, toxicological, and other scientific data that could be useful to the Administrator in carrying out this Act.

"(2) AVAILABILITY.—The Administrator shall make the system available to all Federal and State departments and agencies with responsibilities in the area of regulation or study of pesticides and the effect of pesticides on man and the environment.

"(c) INDEXING.—In designing and implementing the systems required by subsections (a) and (b), the Administrator shall ensure that information submitted before or after the effective date of the Pesticide Reform Act of 1986 is indexed by pesticide name, Chemical Abstracts Service registry number, plant sites by State, and submitter, so that such information may be retrieved in a timely and useful manner.

"(d) CONFIDENTIALITY.—Dissemination of information and data collected under this section to any State or State agencies shall be subject to section 10.

"(e) REPORT.—Not later than 24 months after the effective date of the Pesticide Reform Act of 1986, the Administrator shall submit a report to Congress on—

"(1) progress in designing and implementing the systems required by subsections (a) and (b); and

"(2) the indexing of information in accordance with subsection (c).

"(f) COMPLETION.—Not later than 36 months after the effective date of the Pesticide Reform Act of 1986, the Administrator shall complete the design and implementation of the system required by this section.".

TITLE XXII—AUTHORIZATION OF APPROPRIATIONS

SEC. 2201. AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—Section 32 (as redesignated by section 2101 of this Act) is amended to read as follows:

"SEC. 32. AUTHORIZATION OF APPROPRIATIONS.

"There are authorized to be appropriated to carry out this Act $69,433,100 for the fiscal year ending September 30, 1987, and such sums as may be necessary for each of the fiscal years September 30, 1988, through September 30, 1991.".

(b) EFFECTIVE DATE.—The amendment made by this section shall become effective on October 1, 1986.

TITLE XXIII—TECHNICAL AMENDMENTS

SEC. 2301. TABLE OF CONTENTS.

The table of contents contained in section 1(b) (7 U.S.C. prec. 121) is amended—

(1) by adding at the end of the items relating to section 2(e) the following:

"(5) Noncertified commercial applicator.
"(6) Competent person.";

(2) by striking out the item relating to section 2(n) and inserting in lieu thereof the following:

"(n) Ingredient statement.
  "(1) In general.
  "(2) Common name.";

(3) by adding at the end of the items relating to section 2 the following:

"(ff) Antimicrobial.
"(gg) Importing country.
"(hh) Low volume nonfood pesticide use.
"(ii) Material safety data sheets.
"(jj) Outstanding data requirement.
  "(1) In general.
  "(2) Factors.
"(kk) Pesticide dealer.
"(ll) Pesticide product.
"(mm) Pesticide testing facility.
"(nn) Political subdivision of a State.
"(oo) Terms of registration.
"(pp) To distribute or sell.";

(4) by adding at the end of the items relating to section 3(c) the following:

  "(9) Preregistration access to data.
  "(10) Material safety data sheets.";

(5) by striking out the item relating to section 3(g) and inserting in lieu thereof the following:

"(g) Reregistration of pesticides.
  "(1) In general.
  "(2) Lists of pesticide active ingredients.
  "(3) Priority.
  "(4) Removal.
  "(5) Notification.
  "(6) Judicial review.
  "(7) Data requirements.
  "(8) Filling data requirements.
  "(9) Suspension.
  "(10) Reregistration.
  "(11) Compensation.
  "(12) Lack of essentiality.";

(6) by adding at the end of the items relating to section 3 the following:

"(h) Priority list for inert ingredients.
  "(1) Establishment.
  "(2) Publication of list.
  "(3) Judicial review.
  "(4) Removal of ingredients involving administrative reviews.
  "(5) Removal of ingredients involving additional data.
  "(6) Additional data.
"(i) Substitution of inert ingredients.
"(j) Labeling of inert ingredients.
  "(1) Amended label.
  "(2) Misbranding.
"(k) Formula statements.
  "(1) Listed inert ingredients.
  "(2) All inert ingredients.";

(7) by adding at the end of the items relating to section 4 the following:

"(d) Commercial applicator certification.
  "(1) Criteria.
  "(2) Experience.
  "(3) Additional test.
"(e) Noncertified commercial applicator training and registration.
"(f) Certified and noncertified private applicator training.
"(g) Retraining and recertification.
"(h) Uniform training.

"(i) Training for pesticide applicators and trainers.
  "(1) In general.
  "(2) State program.
  "(3) Private program.
"(j) Worker training.";

(8) by adding at the end of the items relating to section 6 the following:

"(g) Cancellation of registration based on false or invalid data.
  "(1) Previously determined invalid data.
  "(2) New invalid data.
  "(3) False data.
  "(4) Hearing.
"(h) Compensation for data.
"(i) Voluntary cancellation.
  "(1) Requests.
  "(2) Notice.
  "(3) Cancellation.";

(9) by adding at the end of the items relating to section 7 the following:

"(e) Material safety data sheets.
"(f) Confidentiality.
"(g) Information requested.";

(10) by striking out the item relating to section 9(a) and inserting in lieu thereof the following:

"(a) Authority to enter, inspect, and copy.";

(11) by adding at the end of the items relating to section 9 the following:

"(d) Procedure.
  "(1) Credentials and statements.
  "(2) Promptness.
  "(3) Samples.
"(e) Coordination.";

(12) by adding at the end of the items relating to section 10 the following:

"(h) Data disclosure to States.
"(i) Notice.";

(13) by adding at the end of the items relating to section 11 the following:

"(c) Records of commercial applicators.
"(1) Pesticide applications.
"(2) Duration.
"(d) Records of pesticide dealers.
"(1) Pesticide sales.
"(2) Duration.
"(e) Inspection of records.
"(f) Access to records.
"(1) In general.
"(2) Confidential business information.
"(3) Employee access.
"(4) Customer access.";

(14) by adding at the end of the items relating to section 12 the following:

"(c) Liability for pesticide use damage.
"(1) In general.
"(2) Label application.
"(d) Acts of agents.";

(15) by striking out the item relating to section 14(b)(4);

(16) by adding at the end of the items relating to section 14 the following:

"(c) Subpoenas.
"(1) Issuance.
"(2) Jurisdiction.";

(17) by adding at the end of the items relating to section 16 the following:

"(e) Review of regulations.
"(1) In general.
"(2) Court.
"(3) Review of issued regulations.
"(4) Review of refusal to modify or rescind.
"(5) Scope of review.
"(6) Stays.
"(7) Judicial review.";

(18) by striking out the items relating to subsections (a) and (b) of section 17 and inserting in lieu thereof the following:

"(a) Pesticides and devices intended for export.
  "(1) Violations.
  "(2) Exports.
  "(3) Notification.
  "(4) Labels.
"(b) Cancellation notices furnished to foreign government.
  "(1) Issuance.
  "(2) Contents.";

(19) by striking out the item relating to section 20(a) and inserting in lieu thereof the following:

"(a) Research.
  "(1) In general.
  "(2) Integrated pest management.
  "(3) Duplication.";

(20) by adding at the end of the items relating to section 22 the following:

"(c) Effect on certain other laws.
  "(1) In general.
  "(2) Coordination.";

(21) by adding at the end of the items relating to section 23 the following:

"(d) Authorization for appropriations.
  "(1) Certified applicator training.
  "(2) Pesticide certification and licensing programs.
  "(3) Appropriated amounts.
  "(4) Coordination.";

(22) by striking out the item relating to section 24 and inserting in lieu thereof the following:

"Sec. 24. Authority of States.
  "(a) Sale or use.
  "(b) Labeling or packaging.
  "(c) Additional uses.
    "(1) Special local needs.
    "(2) Disapproval.
    "(3) Tolerances or exemptions.
    "(4) Controls.

"(d) Differences in usage and risk.
"(e) Low volume nonfood pesticide use.
  "(1) In general.
  "(2) Informal rule making.
  "(3) Criteria.
  "(4) Duration.
  "(5) Description.";

(23) by striking out the item relating to sections 26 and 27 inserting in lieu thereof the following:

"Sec. 26. State primary enforcement responsibility.
  "(a) State responsibility.
    "(1) Criteria.
    "(2) Coordination.
  "(b) State plans.
  "(c) Administrator responsibility.
  "(d) Certification in pesticide use applications.
  "(e) Political subdivisions.
"Sec. 27. Failure by the State to assure enforcement of State pesticide use regulations.
  "(a) Complaints.
    "(1) Referral.
    "(2) Investigation.
    "(3) Action by Administrator.
  "(b) Rescission.
  "(c) Emergencies."; and

(24) by adding at the end thereof the following:

"Sec. 31. Data collection and retrieval systems.
  "(a) Data collection system.
    "(1) In general.
    "(2) Advisory committee.
  "(b) Data retrieval system.
    "(1) In general.
    "(2) Availability.
  "(c) Indexing.
  "(d) Confidentiality.
  "(e) Report.
  "(f) Completion.".

TITLE XIV—EFFECTIVE DATE

SEC. 2401. EFFECTIVE DATE.

(a) In General.—Except as provided in subsection (b) and other provisions of this Act, this Act and the amendments made by this Act shall become effective 60 days after the date of enactment of this Act.

(b) CERTIFICATION, TRAINING, AND RECORDKEEPING.—The amendments made by sections 101, 107 (only with respect to the definition of "pesticide dealer"), 301, 302, 901, and 1902 shall become effective 120 days after the date of enactment of this Act.

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